HPTN 096

Getting to Zero among Black Men who have Sex with Men (MSM) in the American South: Testing the Efficacy of an Integrated Strategy

DAIDS Document ID: 38561

A Study by the HIV Prevention Trials Network (HPTN)

Sponsored by:
Division of AIDS (DAIDS), United States (US) National Institute of Allergy and Infectious Diseases (NIAID), US National Institutes of Health (NIH)

Non-IND Study

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FINAL Version 3.0
3 August 2023

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PROTOCOL SIGNATURE PAGE

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I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable US Food and Drug Administration regulations; standards of the International Conference on Harmonization Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

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Signature of Investigator Date (DD/MONTH/YYYY)

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LIST OF ABBREVIATIONS AND ACRONYMS

ACCURE	Accountability for Cancer Care through Undoing Racism & Equity
AIDS	acquired immunodeficiency syndrome
AMIS	American Men's Internet Survey
AOR	adjusted odds ratio
ART	antiretroviral therapy
BAC	blood alcohol content
BAI	Black AIDS Institute
BTAN	Black Treatment Advocates Network
CAB-LA	long-acting injectable cabotegravir
CABs	Community Advisory Boards
CAG	Community Advisory Group
CASI	computer-assisted self-interview
CBO	community-based organization
CBPR	community-based participatory research
CDC	Centers for Disease Control and Prevention
CFIR	consolidated framework for implementation research
CI	confidence interval
COVID-19	Coronavirus Disease 2019
CRFs	case report forms
CRISP	Culturally Responsive Intersectional Stigma Prevention
CSG	Community Strategies Group
CV	coefficient of variation
DAIDS	Division of AIDS
DBS	dried blood spot
DHHS	(US) Department of Health and Human Services
ECHO	Extension for Community Healthcare Outcomes
EHE	Ending the HIV Epidemic: A Plan for America
ESAP	Expanded Syringe Access Program
HCCQ	healthcare climate questionnaire
HCF	healthcare facilities
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HPTN	HIV Prevention Trials Network
HRSA	Health Resources and Services Administration
ICFs	informed consent forms
IRB	institutional review board
IRLM	Implementation Research Logic Model
LC	(HPTN) Laboratory Center
LDMS	Laboratory Data Management System
LGBT	lesbian, gay, bisexual, transgender

LOC	(HPTN) Leadership and Operations Center
MOP	(HPTN) Manual of Operations
MSM	men who have sex with men
NIAID	(US) National Institute of Allergy and Infectious Diseases
NIH	(US) National Institutes of Health
NIR	network-individual-resource
OR	odds ratio
nPEP	non-occupational post-exposure prophylaxis
POL(s)	popular opinion leader(s)
PrEP	pre-exposure prophylaxis
PTID	participant ID
QA	quality assurance
QC	quality control
QI	quality improvement
RCT(s)	randomized controlled trial(s)
RR	relative risk
SBPAN	Southern Black Policy & Advocacy Network
SDMC	(HPTN) Statistical and Data Management Center
SDT	self-determination theory
sIRB	single IRB
SMC	(HPTN) Study Monitoring Committee
SMI	social media influencer
SOC	standard-of-care
SSP	Study-specific Procedures (Manual)
STI(s)	sexually transmitted infection(s)
TA	technical assistance
US	United States
VL	viral load

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SCHEMA

Purpose: The purpose of this study is to evaluate an integrated, population-based approach designed to reduce human immunodeficiency virus (HIV) incidence among Black men who have sex with men (MSM) in the southern US by increasing HIV testing, uptake and use of pre-exposure prophylaxis (PrEP) among Black MSM living without HIV, and viral suppression rates among Black MSM living with HIV. A status-neutral approach will be taken such that Black MSM, regardless of HIV status (both those living with and without HIV), will be included in the study.

Design: This study is a community-randomized, controlled, hybrid type III implementation effectiveness study. The study will deliver an integrated strategy that includes a combination of four community-, organizational-, and interpersonal-level components designed to impact individual-level outcomes. A cross-sectional assessment will be conducted at baseline and at the end of the 3-year implementation period. Study endpoints will be assessed using study-collected data, routinely collected HIV surveillance data and commercially available prescription data.

Integrated Strategy Components: The four study components are described below.

- **Health equity:** This community-level structural component will use a standardized, nationally replicable community coalition model (Black Treatment Advocates Networks [BTAN]) to implement an enhanced program model geared to 1) facilitate the effects of the other HPTN 096 interventions by minimizing barriers to HIV testing, PrEP use and viral suppression through sensitizing a local network of service providers (e.g., social, legal, economic sectors) to the needs of Black MSM and maintaining an online platform for exchanging information about the local network that can be used to link Black MSM to resources and services, and 2) amplify the effects of other HPTN 096 components by increasing Black MSM's receptivity to those activities through the integration and promotion of HPTN 096 into the activities of the community coalition model.

- **Social media influencers:** In this community-level component, social media influencers (SMI) will be defined for the purposes of this study as users on social media who have established credibility, trust and access to a large audience of Black MSM, and who can persuade them by virtue of their authenticity and reach. SMI will provide tailored messaging for Black MSM in intervention communities on the topics of:

    - HIV/sexually transmitted infections (STI) testing promotion
    - PrEP (and general HIV prevention) awareness and promotion
    - Definition and benefits of viral suppression.

    Messages may include direction towards health care facilities (HCFs) involved in the intersectional stigma reduction component and information about the virtual peer support platform or BTAN+ events.

- **Intersectional stigma reduction:** This organizational-level component will take place in HCFs and is designed to improve cultural responsiveness in the provision of HIV prevention and health care services to Black MSM. It is expected to contribute to a reduction in HIV incidence by creating an affirming and autonomy-supportive healthcare environment that supports Black MSM engagement in HIV-related care and services and that promotes increased HIV/STI testing, PrEP uptake and viral suppression rates.

- **Virtual peer support:** In this interpersonal-level component, peer support workers will be trained and compensated to provide emotional and practical support services via a virtual platform. These peer support workers will have shared lived experiences with those whom they are supporting, be self-reflective of those experiences, and know when to share those experiences with others in an appropriate and supportive manner. These activities will be closely supervised and managed centrally and will not be directly affiliated with any specific HIV prevention or treatment HCF. Once trained, the peer support workers will have demonstrated competencies in the following domains:

    - HIV, PrEP, non-occupational post-exposure prophylaxis (nPEP), other HIV prevention options and antiretroviral therapy (ART) education
    - Adherence to PrEP, ART and medical care
    - HIV/STI testing
    - New HIV diagnosis
    - Addressing intersectional stigma (anti-Black racism, sexual stigmas, HIV-related stigma)
    - Self-care
    - Information about national and local resources and assistance programs, Black MSM-centered health services, and the cost and insurance coverage of medications (PrEP/ART) and medical care
    - Multicultural competency (as it relates to a range of self-identities and the heterogeneity of the HIV epidemic for Black MSM in the southern US)

Baseline and Post-Implementation Cross-Sectional Assessments: Two cross-sectional assessments will be conducted for this study: one at baseline, the other after the three-year integrated strategy ends (post-implementation assessment). A starfish sampling approach (the combination of venue-time-based and respondent-driven sampling) will be employed to recruit and enroll individual participants in both intervention and control communities. All participants will be offered mail-in HIV test kits, have blood samples collected for HIV status determination, viral load testing, HIV incidence estimation and testing for PrEP use, and will complete two surveys. At a subset of communities, additional blood will be taken for multi-drug testing to evaluate HIV drug resistance testing, expanded HIV incidence assessments, and other exploratory assessments. The purpose of the baseline assessment is to provide data to control for baseline differences, optimize the methodology, and improve the power of the post-implementation assessment. The purpose of the post-implementation assessment is to provide endpoint data for primary, secondary and exploratory objectives.

- **Cross-Sectional Assessment Sample Size:** The baseline cross-sectional assessment will include 100 Black MSM in each of the 8 participating intervention communities and 8 participating control communities for a total of 1600 individuals. The post-implementation cross-sectional assessment will include 200 Black MSM in each of the 16 participating communities (intervention and control) for a total of 3200 individuals.

Study Sites: 16 communities will participate in the study, each made up of one or more counties selected from the southern counties and states identified in the Ending the HIV Epidemic (EHE) plan. The communities will be matched into 8 pairs based on population, HIV prevalence and viral suppression. Within each pair, one community will be randomized by public ceremony to receive the components of the integrated strategy, and the other will serve as the standard-of-care (SOC).

Study Population: The study population for the cross-sectional assessments will be Black MSM in the intervention and control communities. The following study populations will be prioritized for each component of the integrated strategy:

Health equity:	Black MSM and local community
Social media influencers:	Black MSM
Intersectional stigma reduction:	Healthcare facility staff
Virtual peer support:	Black MSM

PrEP Provision: In order to support HIV prevention in Black MSM and to engage both intervention and SOC communities, HPTN 096 will provide PrEP, and potentially ART for treatment, to at least one facility in each community.

Study Duration: Study duration is approximately 6 years total. After a one-year implementation ramp-up phase prior to the start of the implementation period, the integrated strategy will be delivered over three years. The cross-sectional assessments will be conducted prior to and immediately following implementation of the 3-year integrated strategy. Each assessment will take approximately 6 months to complete, and the baseline assessment will take place during the ramp-up period. Laboratory testing, data analysis, and analysis of surveillance data will require approximately 1.5 years after completion of the post-implementation assessment.

Study Objectives:

Primary Study Objectives:

- To increase the proportion of Black MSM living with diagnosed HIV who are virally suppressed (<200 copies/mL) in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on HIV surveillance data

- To increase PrEP use by Black MSM not living with HIV in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment

Secondary Study Objectives:

- To compare self-reported HIV testing behavior in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on the post-implementation cross-sectional assessment

- To compare social support, intersectional stigma, barriers to healthcare, and individual agency in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on the post implementation cross-sectional assessment

- To increase the proportion of Black MSM living with HIV newly diagnosed in the past year who are virally suppressed (<200 copies/mL) within six months of diagnosis in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on HIV surveillance data

- To track ongoing EHE implementation activities for Black MSM (e.g., outlined by the EHE plans) of both intervention and control communities (used for adjustment in analyses and to assess implementation outcomes of acceptability/compatibility)

- To assess measures of care quality, and care responsiveness to Black MSM needs at HCFs participating in the Culturally Responsive Intersectional Stigma Prevention (CRISP) component, pre- and post-implementation (used to assess service outcomes)

Exploratory Objectives:

- To compare the estimated HIV incidence in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment

- To compare use of antiretroviral drugs by Black MSM living with HIV in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment (this analysis will be limited to a subset of communities)

- To compare HIV drug resistance in Black MSM living with HIV in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment (this analysis may be limited to a subset of communities)

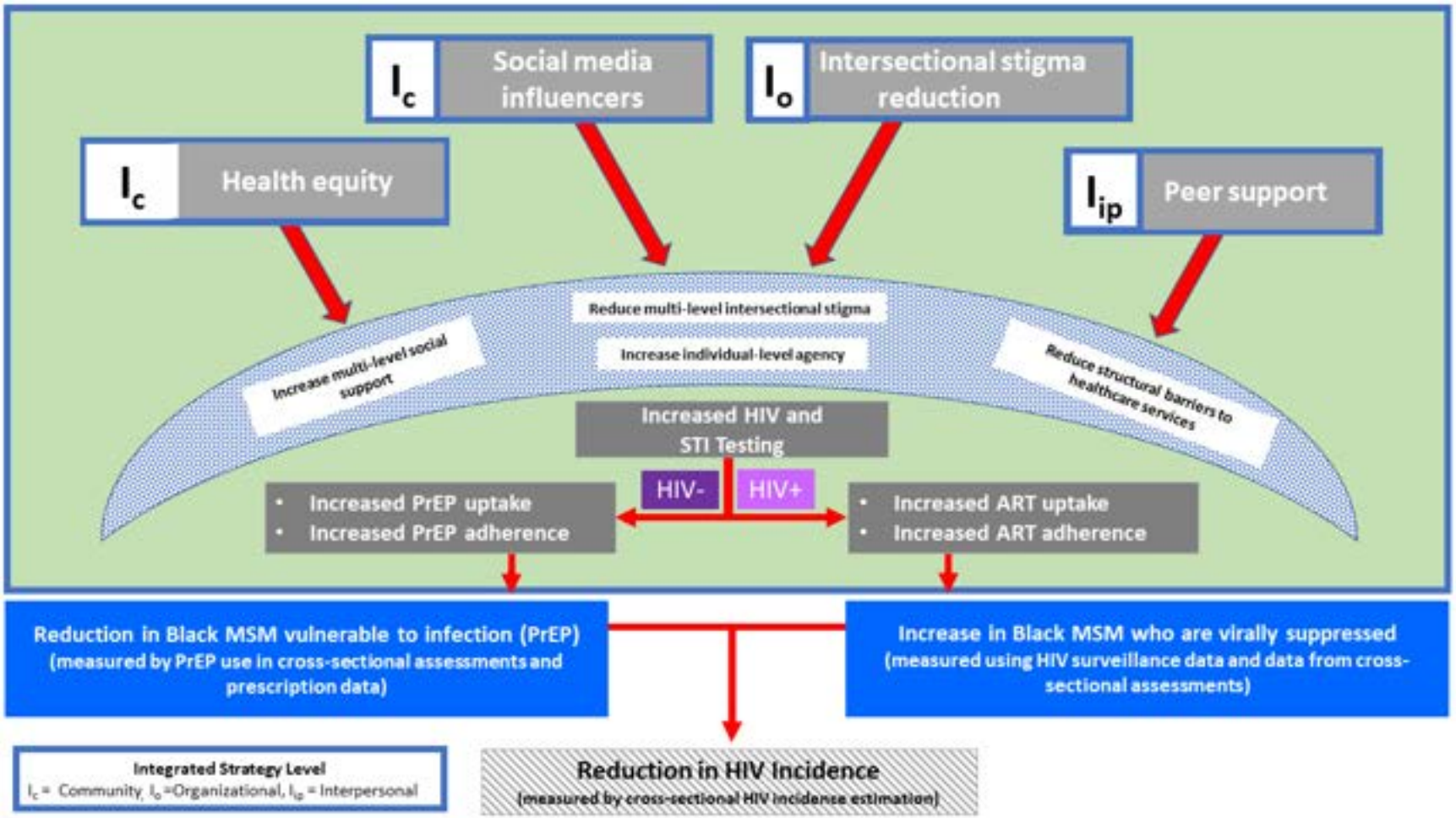
To use mathematical modeling to

  - inform interim analysis by using HIV surveillance data on viral suppression during the trial to predict the expected impact on HIV incidence at the end of the trial
  - estimate the longer-term impact of the integrated strategy on HIV incidence among Black MSM in the southern US
  - estimate the contribution to the overall impact on HIV incidence made by each of the integrated strategy components

- Using attribution analysis, estimate the contribution made by each of the integrated strategy components (health equity, social influencers, intersectional stigma reduction, and peer support) to changes in viral suppression and PrEP use among Black MSM in the southern US

- Stored specimens may be used for laboratory assessments that include phylogenetic analysis of HIV in the study communities; characterization of HIV; development, validation, evaluation of laboratory assays relevant to the HIV epidemic and study objectives, and testing associated with SARS-CoV-2 and other related viruses.

Schema Figure 1: Overall HPTN 096 Study Design



1.0 INTRODUCTION

1.1 Background

Men who have sex with men (MSM) bear the most disproportionate burden of human immunodeficiency virus (HIV) incidence and prevalence of any community in the US (1). Despite accounting for only 2-3% of adults in the US, gay, bisexual and other MSM accounted for more than 70% of new HIV diagnoses in the US in 2018 (2). Within this relatively small and highly burdened population there are also racial health disparities. Black MSM accounted for 37% of all new diagnoses of HIV infection among MSM, despite accounting for only 12-13% of all US MSM (2). Geographic disparities also exist with this racial disparity; nearly two thirds (63%) of all US Black MSM with diagnosed HIV infection reside in the southern US (2), making HIV prevention activities for Black MSM in this region critical. An added concern for primary prevention is that young MSM of color have the highest HIV incidence densities of any MSM subgroup (1). In 2018, young people accounted for 21% of the new HIV diagnoses in the US, with most being among young gay and bisexual men (3). Youth aged 13 to 24, in particular, accounted for more than 1 in 5 these new HIV diagnoses (3, 4). The period of adolescence is a time when young people have increasing independence and accountability for their own individual sexual and reproductive health and well-being (5, 6); relatedly, research shows that stigma, homophobia, and discrimination put young MSM at increased risk for poor prevention and treatment outcomes and can affect whether they seek or receive quality health services, including HIV testing, treatment, and other prevention services, including PrEP (7). This environment leads to higher rates of undiagnosed or unsuppressed HIV and increased risk for HIV acquisition (8).

The epidemiology of HIV in the US demands that we prioritize Black MSM for intensified testing, prevention and treatment. The imperative of equity, and to reduce HIV stigma in terminology, demands that we use the term ‘living with HIV’ rather than terms like “HIV-infected”, to describe the community we seek to serve.

In the era of widely available HIV testing, highly effective antiretroviral therapy (ART), and effective biomedical prevention of sexual transmission between men in the form of pre-exposure prophylaxis (PrEP), the HIV epidemic among this community persists. Health inequalities continue to drive poor outcomes in diagnoses, prevention, and care for Black MSM across the prevention and treatment continua. At a time of heightened awareness of racial injustice and the many social and health impacts of structural anti-Black racism in the US, these stark health inequalities are increasingly understood as the outcomes of social determinants of health that must be addressed if we are to achieve meaningful improvements in outcomes for these men and their communities.

A large number of publications in the epidemiologic, sociologic, and health services literature have described and investigated these inequities and sought to understand and address them. The findings across multiple disciplines have been consistent — individual level behaviors play only modest roles in risks for infection and poor clinical HIV outcomes. The critical drivers for HIV outcomes among Black MSM and their communities are social, structural and health care system level ones — what are often referred to as the structural determinants of health (9-11). Lower levels of health care access and insurance, lower rates of disease screening, poverty, and

intersectional stigma, including stigma in health care settings, all play determinative roles in the longstanding health inequities seen among Black MSM.

Yet interventions that seek to address the structural determinants of health for Black MSM have been few, and none have been studied in community randomized controlled trials. HPTN 096 is a pioneering integrated strategies trial that seeks to improve outcomes for Black MSM in HIV testing, prevention, and treatment across the most HIV-affected region in the country—the South.

1.1.1 HIV Epidemic in the Southern US

The epidemiology of HIV in the US shows an increasing concentration of the epidemic in a relatively small number of high prevalence ("hot spot") zones. The US has over 3100 counties, but just 48, along with the District of Columbia and Puerto Rico, accounted for more than half of all new HIV diagnoses in 2017 (12). The South has roughly one-third of the US population but accounted for 51% of new infections in 2018 (13). This is also the region with many of the lowest rates of health care access and health insurance, since many southern state governments chose not to expand health care insurance for low income citizens through the Medicaid expansion component of the Affordable Care Act (14). In this region, both HIV testing (15) and viral suppression rates (16) are lower and, in many communities, stigma and discrimination based on race, ethnicity, and sexual and gender minority status remain high (17). All of these factors have been described as part of a syndemic of multiple overlapping risks and vulnerabilities that have generated and maintain this striking health inequity (18). The persistence of structural racism in the region, including disparities in housing, economic opportunity, high rates of arrest and incarceration, and the current social reckoning with these realities underway across the country, have heightened the awareness that interventions by and for Black MSM must be based on the recognition that the legacies of the past must be addressed to make lasting change in health equity and access.

1.1.2 Ending the HIV Epidemic Initiative

HPTN 096 has been designed to strategically align with the recently announced US federal initiative "***Ending the HIV Epidemic: A Plan for America,"*** referred to as EHE. The EHE plan is based on the current epidemiology of HIV in the US (19). The plan asserts that we now have the scientific and public health tools to end HIV in the US by 2030, but that a relatively small number of high transmission jurisdictions will require greatly intensified efforts to reduce the health disparities at the heart of the US epidemic. As such, the plan identifies the 48 counties, Washington, DC and San Juan, Puerto Rico (which collectively account for over 50% of new HIV infections), as well as seven states with disproportionately high HIV incidence in rural areas, as the priority areas for these intensified EHE efforts (12). The plan also recognizes, in the words of Secretary Azar of the US Department of Health and Human Services (DHHS), that "…stigma, which can be a debilitating barrier preventing someone living with HIV or at risk for HIV from receiving the healthcare, services, and respect they need and deserve—still tragically surrounds HIV" (20). Four key areas are targeted for funding increases to implement the plan: ***Diagnose,*** increase the proportion of Americans living with HIV who know their status and link them immediately to care; ***Treat,*** rapidly and effectively achieve viral suppression; ***Prevent,*** rapidly increase the proportion of at-risk persons on PrEP; and ***Respond,*** detect and respond to

HIV clusters and prevent new infections. HPTN 096 will address the first 3 pillars of EHE in its integrated strategy.

A number of federal agencies are tasked with engagement in the EHE plan and with its implementation including the NIH, Centers for Disease Control and Prevention (CDC), and Health Resources and Services Administration (HRSA). NIH, specifically the Division of AIDS (DAIDS) within the National Institute of Allergy and Infectious Diseases (NIAID), will lead the research effort for EHE, which centers on implementation science for the plan. The CDC and HRSA efforts in these counties will be led and funded by the respective agencies, with CDC taking a lead in enhancing diagnoses and prevention efforts, and HRSA, through its Ryan White Program, supporting enhanced treatment and viral suppression outcomes. HPTN 096 is sponsored by the NIH and will be a collaborative partnership with the other federal agencies above, namely CDC and HRSA. The study will engage with 16 communities (some comprised of multiple counties) selected from among the 28 southern EHE counties; Washington, DC; and the six southern EHE states (see Section 4.1 for additional detail). HPTN 096 will enhance these ongoing EHE efforts by adding "Getting to Zero in the American South," a four-component integrated strategy with interpersonal, organizational and community level components.

1.1.3 Proven HIV Prevention Methods: HIV Testing, PrEP, and Viral Suppression

There now exists an evidence-based repertoire of biomedical strategies for HIV prevention that include rapid and self-testing for HIV, PrEP for those who are not living with HIV but are at risk of acquiring HIV, and effective ART and treatment as prevention for those living with HIV. Yet, it has been known for years now that many people – particularly those affected by health, social, and economic disparities – are left behind in the HIV prevention and treatment continua (21). Identifying people living with HIV who are unaware of their HIV infection status and linking them to care services, linking those not living with HIV to prevention services, and reducing health disparities are important national HIV prevention and treatment goals (22).

1.1.3.1 HIV Testing

In 2016, analysis of CDC-funded HIV testing data for MSM from 20 health departments in the southern US revealed that Black MSM received 6% of HIV tests while accounting for 36% of new diagnoses in non–HCFs (23).

The CDC encourages health departments to consider HIV self-testing as an additional testing strategy to reach persons most affected by HIV (24). There is sound evidence to support the benefits of HIV self-testing. For example, a national randomized controlled trial (RCT), the "eSTAMP" study, was designed to evaluate the public health benefits of mailing HIV self-tests to internet-recruited gay, bisexual and other MSM in the US during 2015 and 2016 (25, 26). Compared to men in the control arm, men who were mailed HIV self-testing kits tested themselves more frequently and had a significantly higher rate of HIV positivity. There was also no difference in sexual risk behaviors. In addition to using HIV self-tests themselves, participants were able to share the study HIV self-test with members of their social network, resulting in many more persons becoming aware of their HIV infection. While 42% of the sample was from the South US Census Region, only 10% of the sample was Black.

Increasing awareness of HIV status through HIV testing, especially among Black MSM in the South, is essential for reducing the risk for transmission and addressing HIV related health disparities. HIV testing programs in the South can reach more Black MSM by conducting targeted risk-based testing in non–health care settings and by routine HIV screening in agencies that also provide health care services to Black MSM. HIV self-testing provides greater access by allowing people to take an HIV test and find out their result in their own home or other private location. Self-testing increases the options for Black MSM to know their HIV status, and, along with clinic and community-based testing, is paramount and an essential starting place for achieving EHE goals.

1.1.3.2 PrEP

Several randomized clinical trials have demonstrated the efficacy of PrEP in preventing HIV acquisition (27, 28). The CDC recommends PrEP as an HIV prevention strategy, based on evidence that taking PrEP medication as prescribed reduces the risk of HIV transmission via sexual contact by about 99% (29). Currently there are two medications - emtricitabine and tenofovir disoproxil fumarate (Truvada), and emtricitabine and tenofovir alafenamide (Descovy) - approved for daily use as HIV PrEP. Furthermore, although an off-label use, on-demand oral PrEP is highly effective at preventing HIV infection among high-risk MSM, is endorsed for MSM by the WHO (30) (although not yet by the CDC (31)), and represents an alternative to daily PrEP and expanding choices for HIV prevention (32). However, racial disparities remain, with Black MSM consistently demonstrating lower levels of PrEP awareness, access, and utilization, compared to White MSM (33). Also, healthcare system barriers and intersecting stigmas (PrEP-stigma, HIV-stigma, homophobia, and anti-Black racism) are prevalent, with limited interventions developed to address these barriers (34). Recent and exciting results from HPTN 083, a global randomized, controlled, double-blind study that compared the safety and efficacy of long-acting injectable cabotegravir (CAB LA) to daily oral Truvada PrEP, showed that CAB LA lowered HIV incidence among cisgender men and transgender women who have sex with men (35), and was superior to daily oral Truvada. It is likely that CAB-LA will be approved for general use soon, thus providing an added alternative to oral PrEP. It is critical to ensure that Black MSM in the South have equitable access to all available HIV prevention strategies, including PrEP.

1.1.3.3 Viral Suppression

HIV testing and prompt linkage to and retention in HIV medical care are essential to achieve viral suppression among those persons living with HIV who are unaware of their infection and those who are aware but not in care. It is now well established that early ART initiation carries clear short and long-term benefits to the person living with HIV (36) and also significantly contributes to reduced onward transmission of HIV to sexual partners when there is sustained viral suppression (37). As with HIV testing and PrEP, disparities exist among Black MSM with ART access, uptake, and retention. In an analysis of seven studies from Canada, 13 from the UK, and 174 from the US, Black MSM in each country were less likely to initiate combination ART compared to other MSM living with HIV. US Black MSM living with HIV were also less likely to have health insurance, have a low CD4 count, adhere to ART, or be virally suppressed than were other US MSM living with HIV (21). There were also greater structural barriers (i.e., unemployment, low income, previous incarceration, less education) associated with poor HIV

health outcomes among Black MSM compared to other MSM (21). These structural factors affect availability and choice of sex partners and are also associated with living in neighborhoods with a high background HIV prevalence and community viral load, which raises infection risks for sexually active persons. Elimination of disparities in HIV infection in Black MSM cannot be accomplished without addressing social determinants of health associated with HIV clinical care access and outcomes, an important focus of our integrated strategies approach in HPTN 096.

1.1.4 HIV Surveillance Data for Community Randomized Design

HPTN 096 will use data from the CDC's National HIV Surveillance System to measure the outcomes of both primary and secondary objectives, in addition to data from the baseline and post-implementation cross-sectional assessments and data from commercially available prescription databases. The CDC maintains the National HIV Surveillance System, which is the primary source of data for monitoring HIV-related trends in the US (38). The CDC does this by funding and assisting state and local health departments to collect information about the incidence and prevalence of HIV infection. In turn, these health departments report de-identified data to the CDC so that HIV-related information from around the country can be consolidated and analyzed. Some of the critical parameters collected include basic demographic information (e.g., age, race, gender), date of diagnosis, acquisition risk and laboratory values (CD4 and viral load measurements) (38). The ultimate goal of this surveillance system is to provide an integrated database that includes HIV infection, disease progression, and the behaviors and characteristics of people at high risk. The CDC uses this living database to understand the HIV epidemic in the US and to direct HIV prevention and treatment funding where it is needed most.

In addition to guiding public health policy, the CDC's National HIV Surveillance System can be used for research purposes, as data are continuously collected in a prospective manner. As the data are geographically linked, they can be categorized by location (e.g., state, county, city, facility), which allows the data to be used to measure outcomes for interventions made at the community-level. HPTN 065, another integrated-strategy protocol, used HIV surveillance data to compare two financial incentive interventions across HIV testing and care facilities in Washington, DC and the Bronx, NY (39, 40). In this study, facilities were randomized to the intervention or control arm, and laboratory values from the surveillance system were used for outcome analysis, which compared the percentage of those linked to care and the percentage of those who achieved and maintained viral suppression across arms.

The use of surveillance data for this study is feasible because all of the study communities are contributing data to the CDC's National HIV Surveillance System. For the primary objective, viral load data from diagnosed Black MSM who are alive at the end of each year will be used to compare rates of viral suppression between the intervention and control communities at baseline, annually throughout the intervention period and at the end of the study. For one of the secondary objectives, the date of new HIV diagnoses and viral load data from Black MSM who are alive at the end of each year will be used to determine if the intervention is able to increase the proportion of Black MSM who are virally suppressed within six months of diagnosis compared to the control arm.

1.1.5 HPTN 096 Development and Implementation in the Context of the COVID-19 Epidemic

The ongoing and severe epidemic of SARS-CoV-2 and the disease it causes, COVID-19, has disrupted and challenged virtually every aspect of social life in the US, impacting our health system, preventive services, and social services. All of the integrated strategy components, as well as recruitment and sampling for the cross-sectional assessments, are adaptable to the virtual and socially distanced reality of our country in 2020 and into the foreseeable future as long as COVID-19 persists. Even with effective vaccines available, we estimate that limited access to them will persist throughout 2021 and potentially longer. While the future of the epidemic and of the response is unpredictable, the study has been developed with the expectation that a significant majority of study activities will be conducted virtually and that those elements requiring direct participant contact, such as the baseline and post-implementation blood draws as part of the cross-sectional assessments, will be done while maintaining appropriate safety precautions, social distancing, and maximal possible protection for study staff, participants and investigators.

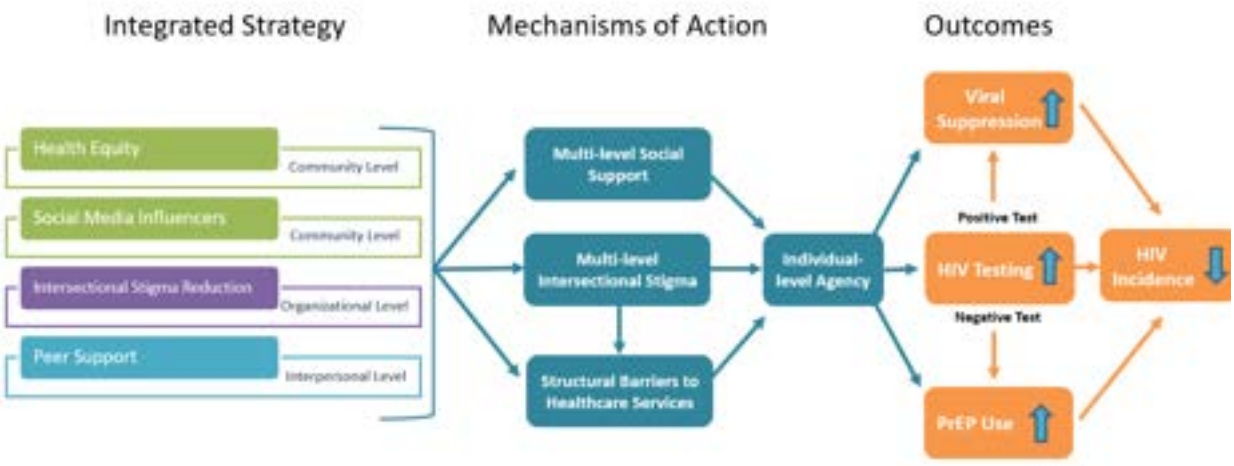
1.2 Rationale for an Integrated Strategy Approach

HPTN 096 is based on scientific and programmatic evidence that individual-level behaviorally-focused interventions alone are insufficient to have a population effect on HIV incidence among Black MSM (41-43). While highly efficacious biomedical HIV prevention tools—such as HIV PrEP—are available to consumers within the healthcare market (44-46), its broad availability alone has not translated into prevention gains for Black MSM (47, 48), despite evidence that Black MSM are interested in and willing to take PrEP (49, 50). Cost is a known barrier to accessing PrEP and other healthcare services, but other evidence indicates that anti-Black and anti-gay attitudes, as well as the prescribing practices of healthcare providers, are also barriers for Black MSM's access to these products and services (49, 51). These attitudes are manifested in institutional policies and practices of HCFs and HCF staff and are not isolated phenomena, but reflect larger social attitudes that stigmatize Blackness, gayness, HIV seropositive status and HIV-related health seeking behaviors. In sum, the key factors driving HIV infection among Black MSM operate at multiple levels that intersect to reinforce barriers that undermine HIV testing, uptake of biomedical HIV prevention, treatment engagement, and viral suppression goals (52-54). These levels include community, organizational and interpersonal levels.

The overall approach to HPTN 096 is based on a socioecological framework (Figure 1) (55, 56) and utilizes the convergence framework (Figure 2) (57) for integrating strategies across multiple levels.

Figure 1. Socioecological framework in HPTN 096

Figure 2. Theorized Pathway of Integrated Strategy Effects on Study Outcomes



The four components will be combined into one integrated strategy implemented to address the multi-level drivers of HIV incidence in Black MSM. Intervening at multiple levels is needed because structural inequities, community-level stigma norms, intersectional stigma in HCFs, and decreased access to peer-based social support act interdependently to impede HIV testing, PrEP use and HIV viral suppression; therefore, intervening at a single level—while necessary—is insufficient to achieve population-level reductions in HIV incidence among Black MSM (58).

Community Level – *Structural Inequities in Local Municipalities Are Barriers to HIV Prevention and Care.* Data from HPTN 061 identified economic, social and legal hardships

across six sites that were associated with increased HIV/STI risks among Black MSM (59). These economic (e.g., job loss, recent financial crisis) and social (e.g., unstable housing) hardships may have particular salience for HIV prevention and care among Black MSM in communities without robust social safety net programs. Other social hardships (e.g., no health insurance) can have a more severe impact on Black MSM who are unemployed in states without Medicaid expansion programs. HPTN 061 also found very high levels of police contact among Black MSM (60), with an estimated incarceration incidence of 35% (95% confidence interval [CI] 31-38) during the study period (54). Black MSM who reported legal hardships (i.e., recent conviction) were more likely to have an STI in the past 6-months (adjusted odds ratio [AOR]=3.97; 95% CI 1.58-9.94) (59). In another national sample of Black MSM (*N*=1,172), a high percentage (43%) reported police discrimination that was associated with recent arrest (61). Recent arrest and an incarceration history were both associated with sexual risk. Additionally, incarceration and recent arrests were associated with lower willingness to use PrEP (61). The impacts of these structural inequities on HIV incidence are problems that are not solved by HIV testing, PrEP use, or treatment access alone; on the contrary, structural inequities thwart the attempts of Black MSM to prioritize HIV prevention and care approaches due to other daily, tangible and immediate threats to their health and survival (62, 63). Consequently, health equity promotion approaches that engage multi-sectoral coalition building are needed to mitigate the impact of structural inequities on HIV testing, PrEP use and viral suppression among Black MSM.

Community Level – *Stigmatizing Attitudes and Social Norms Against Black MSM Undermine Health Seeking Behaviors.* Black MSM who live in the South must make decisions whether to seek healthcare services in social contexts where their race, in addition to disclosure of their health status, health seeking behavior (e.g., using PrEP) or sexual orientation can make them the subject of mistreatment, discrimination and harassment. In addition, these stigmatizing attitudes are sometimes applied directly to the products (e.g., PrEP), services (e.g., HIV testing) or HCFs (e.g., lesbian, gay, bisexual, transgender (LGBT)-centered care) themselves, which can lead Black MSM to evade prevention services to avoid the stigma and potential material consequences (e.g., job loss, housing loss) of being associated with them. Moreover, these community-level attitudes can be internalized by Black MSM themselves and increase the likelihood of HIV infection (64). Social media has emerged as a powerful platform that can be leveraged to positively influence community-level social norms—counteracting the intersectional stigma attitudes and norms that undermine HIV prevention and treatment outcomes for Black MSM.

Organizational Level – *HCF Policies, Practices and Staff Attitudes and Behaviors Impede Access and Retention in HIV Prevention and Treatment Services.* HCFs are selected as one of the targets for integrated strategy because, even if Black MSM are sufficiently motivated to seek an HIV test, attempt to access PrEP or HIV treatment services, these are typically performed in an HCF. The socio-environmental conditions in HCFs can either be synergistic or antagonistic to the men's motivation to test for HIV, engage in PrEP services or engage in treatment services (65, 66). There are a number of studies documenting that intersectional stigma embedded in attitudes, logics and practices of healthcare workers actively impede access to HIV-related services (including HIV testing and PrEP) and undermine the quality of healthcare encounter

experience and, consequently the diminishes the effectiveness of care in improving health (51, 65, 67, 68).

Interpersonal Level – A peer support component was chosen because of the positive influence that Black MSM can have on one another. Peers can positively influence health behaviors of other Black MSM as well as address the potential negative influence of enacted and internalized forms of intersectional stigma (anti-Black racism with HIV stigma and sexual stigmas) (69-74). Another key reason that the HPTN 096 integrated strategy is targeted to the interpersonal-level is because chronic exposure to stigma (whether at the larger community-level or the organizational-level) can lead to internalization of the stigmas, which can impede HIV testing and prevention service engagement (75-77). Stigma can also compromise psychological well-being due to the gender role strain that Black MSM may experience in response to pressures from peers and families to conform to expectations of masculinity that can often conflict with sexual identity expression (78). Incongruence between one's sexual and racial identity was associated with increased odds of condomless receptive anal intercourse (odds ration [OR]=1.38; 95% CI: 1.22, 1.55) and HIV infection (OR=1.22; 95% CI: 1.06, 1.41) among Black MSM in HPTN 061 (64). Peer-support is designed to combat the internalization of stigma through the provision of affirming, educative and emotionally supportive encounters with other Black MSM, while also guiding men towards culturally appropriate and comprehensive health and social services and supporting PrEP and ART initiation and adherence.

Table 1 details the levels of intervention and outcomes described above.

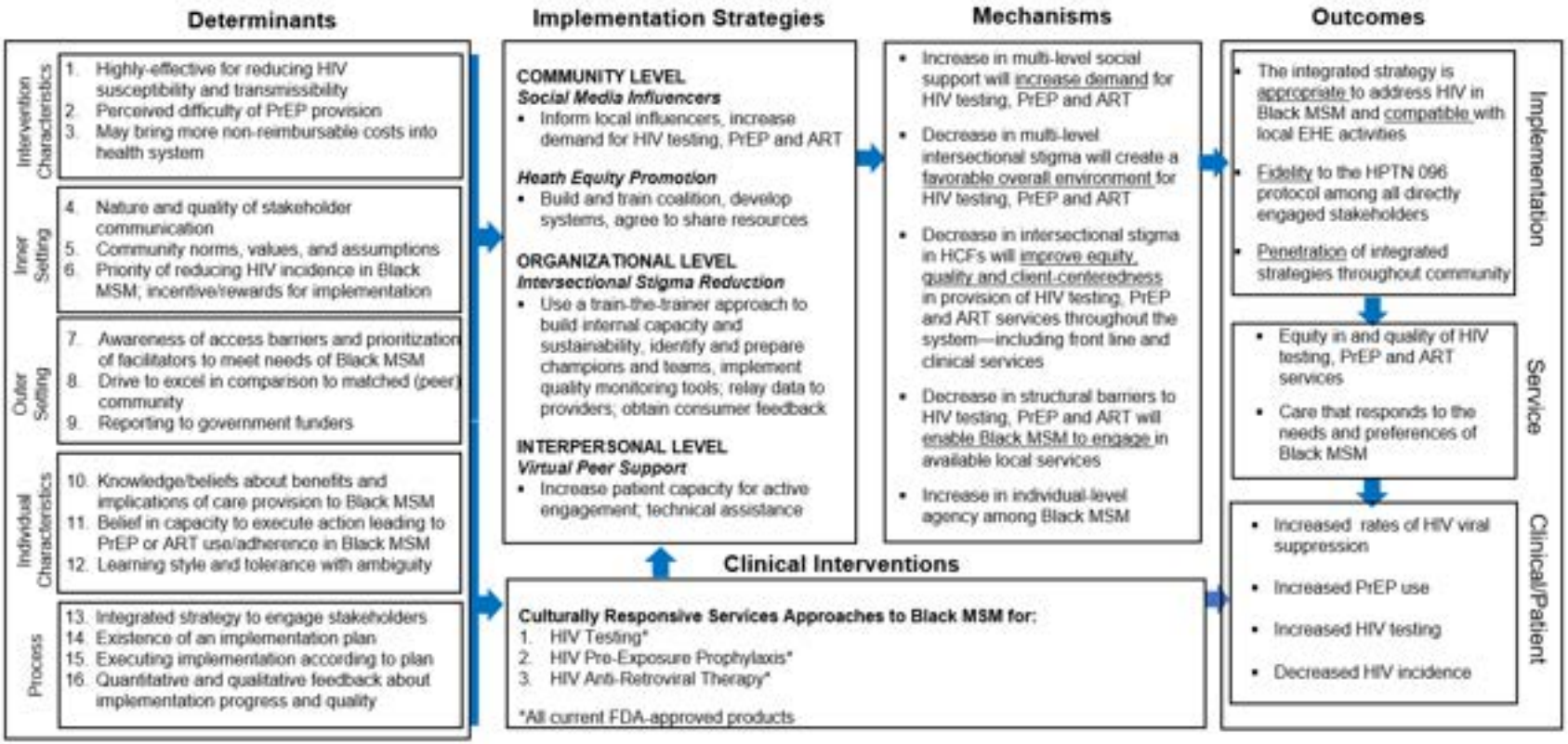
Table 1. Levels, Drivers, Integrated Strategy Components and Interventions for HPTN 096

LEVEL	DRIVER	COMPONENT	INTERVENTIONS IMPACTED		
			Testing	PrEP	Viral Suppression
Community	Structural inequities manifested through economic, social and legal hardships that impede HIV prevention.	Health Equity	Indirect	Indirect	Indirect
Community	Stigma and social norms non-supportive of HIV-related service use.	Social Media Influencers	Indirect	Indirect	Indirect
Organizational	Stigma that is institutionalized in policies and practices of HCFs and staff.	Intersectional Stigma Reduction	Indirect	Indirect	Indirect
Interpersonal	Internalized stigma Lack of social support.	Virtual Peer Support	Indirect	Indirect	Indirect

1.2.1 The Implementation Research Logic Model: A Method for Explaining the Influence of the Integrated Strategy on Clinical Interventions and Study Outcomes

HPTN 096, as previously described, is a classic community-randomized controlled trial. It will include assessments of the effect and impact of an integrated strategy of three locally implemented clinical interventions (HIV testing, PrEP use/adherence, ART use/adherence) on rates of HIV viral suppression and PrEP use among Black MSM. This is classified in the literature as a hybrid type III implementation-effectiveness study (79)**.** We employ the Implementation Research Logic Model (IRLM) as an explanatory method that accommodates the hybrid implementation-effectiveness character of HPTN 096 (80) by framing the relationships between the implementation strategies, the clinical interventions, the mechanisms of action and the study outcomes (implementation, service, and clinical). Our use of an implementation science framework necessitates that we define "the communities" as the site of implementation. We also take into account the theorized pathway of the integrated strategy's effect on the study outcomes (Figure 2) and situate it within the context of implementation determinants, implementation outcomes and service outcomes (Figure 3). Together these are the core elements of the IRLM: clinical interventions, determinants, strategies, mechanisms and outcomes.

Figure 3. HPTN 096 Implementation Research Logic Model



Clinical Interventions are evidence-based practices that have been shown through rigorous research testing to have efficacy in producing a particular health outcome. In HPTN 096, the three interventions are HIV testing, which has been shown to be able to definitively identify or rule out an HIV infection, PrEP, which has demonstrated efficacy in prevention acquisition of an HIV infection, and ART, which has demonstrated efficacy in suppressing viral load and preventing the onward transmission of HIV.

Determinants are factors that can either impede or facilitate the effective local implementation of the adoption of the clinical intervention. The IRLM uses determinants drawn from the consolidated framework for implementation research (CFIR) (81). These determinants are categorized into five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals and process. These five domains are represented in the HPTN 096 IRLM (Figure 3). We identified 16 relevant determinants from across the five domains. The general conceptual CFIR definitions of each of the selected determinants used in HPTN 096 are listed below. Their corresponding operational descriptions are listed in the HPTN 096 IRLM (Figure 3).

Intervention Characteristics

- Relevant Advantage – Stakeholder's perception of the advantage of implementing the intervention versus an alternate solution.
- Complexity – Perceived difficulty of implementing the intervention reflected by the radicalness, disruptiveness, and intricacy of the steps required to implement.
- Cost – Costs of the intervention or costs associated with its implementation.

Inner Setting

- Networks and Communication – The nature and quality of webs of social networks and the formal and informal communications in the implementation context.
- Culture – Norms, values and basic assumptions in the implementation context.
- Implementation Climate/Relative Priority – The shared perception of the importance of the intervention and the extent to which the use of the intervention will be supported and rewarded within the implementation context.

Outer Setting

- Patient Needs and Resources – The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized in the implementation context.
- Peer Pressure – Competitive pressure to implement an intervention, typically because key peer implementers have already implemented or are trying to gain a competitive edge.
- External Policies and Incentives – External strategies to spread interventions, including external mandates and public or benchmarking reporting.

Characteristics of Individuals

- Knowledge/Beliefs about Intervention – Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths and principles related to the intervention.
- Self-Efficacy – Individual's belief in their own capabilities to execute course of action to achieve implementation goals.
- Tolerance of Ambiguity/Learning Style – The degree to which implementers are able to cope with and benefit from any needs to "learn as you go" versus knowing in advance exactly what are all the steps.

Process

- Engaging – Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, training and other similar activities.
- Planning – The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and is high quality.
- Executing – Carrying out or accomplishing the implementation according to plan
- Reflecting and Evaluating – Quantitative and qualitative feedback about the progress and quality of the implementation accompanied with regular debriefing on the experience.

Implementation Strategies are techniques and methods used to optimize the implementation of clinical interventions, including products/tools, programs or healthcare practices (82). Strategies optimize the local implementation of clinical interventions by addressing determinants—either mitigating determinants that impede implementation or enhancing determinants that facilitate intervention implementation (83). Research has identified a great number of potential implementation strategies (82, 84). In HPTN 096, we selected strategies from among the 73 identified in the Expert Recommendations for Implementing Change project (82). Detailed background (see Section 1.2.3), theoretical rationale (see Section 1.2.4) and description of each component of the integrated strategy (see Sections 5.0, 6.0, 70, 8.0) are presented in subsequent Section of this protocol. Figure 3 itemizes the specific discrete activities involved in each component of the integrated strategy.

Mechanisms of Action are the ways in which the implementation strategies are theorized to impact on outcomes. The mechanisms of action of HPTN 096 are shown in Figures 2 and 4.

Outcomes. In using the IRLM, we are concerned with effecting three types of outcomes. Implementation outcomes are the indicators of the success of the process of implementing the integrated strategy and precedes service outcomes and clinical outcomes. Services outcomes relate to the quality of clinical operations and/or patient care which should be positively affected by successful implementation. The implementation and service outcomes selected for HPTN 096

are drawn from the research evidence-base (80, 85, 86) as well as formative information gained from our consultations with community stakeholders and EHE councils from across the south. Clinical outcomes are individual/patient-level indicators directly impacted by the optimized implementation of the clinical interventions. The general conceptual definitions of each the selected implementation and service outcomes used in HPTN 096 are listed below. Their corresponding operational definitions are listed in the HPTN 096 IRLM (Figure 3).

Implementation Outcomes

- Appropriateness – The perceived fit of the innovation or evidence-based practice to address a particular issue or problem (80, 86).
- Fidelity – The degree to which an intervention was implemented as prescribed in the protocol or as it was intended by the program developers (80, 86).
- Penetration – The integration of a practice within an implementation setting (80, 86).

Service Outcomes

- Equity – Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status (86).
- Patient-centeredness – Providing care that is responsive to individual patient preferences, needs and values (86).

Clinical Outcomes.

- In HPTN 096 these are what we have described in this protocol as our primary study objectives—that is—viral suppression and PrEP use among Black MSM.

1.2.2 Primacy of Community Engagement for an Integrated Strategy

The HPTN 096 integrated strategy also builds skills, supports collective efficacy and harnesses sociocultural assets in Black communities to mobilize coalitions and collective action to identify and address barriers to HIV testing, PrEP use and viral suppression among Black MSM (63, 87). The study team used a community-based participatory research (CBPR) (88, 89) approach by conceptualizing HPTN 096 in collaboration with broad and frequent input from gay-identified and non-gay identified Black MSM—including same-gender loving Black men—from communities across the South. The CBPR approach to engaging with community members began with identifying forums where Black MSM, allies and stakeholders were convening to specifically discuss strategies to improve the health and wellness of Black MSM. The first formal step in the HPTN 096 CBPR process was a consultation of Black LGBT community stakeholders convened by the HPTN 096 co-chairs during the 2019 National HIV Prevention Conference (Atlanta, Georgia). The consultation included representatives from the HPTN Black Caucus, the Black Gay Research Group, National Black Gay Men's Advocacy Coalition, Southern Black Policy & Advocacy Network (SBPAN), Abounding Prosperity Inc., The House of Blahnik Inc., Thrive Support Services, Inc., Us Helping Us, Inc., and others. This initial engagement was followed by a series of onsite community listening sessions including the 2019

National CFAR Community Advisory Board Meeting (Chapel Hill, NC), the 2019 Saving Our Selves/SOS conference (Charleston, South Carolina), the 2019 Southern Region Ball House & Pageant Conference (Dallas, Texas), and the 2019 South Carolina MSM HIV Prevention Institute (Columbia, South Carolina). The prioritization of Black MSM voices in the development of the protocol was key to ensuring the integrated strategy advanced beyond addressing individual-level behavioral factors towards addressing social/structural impediments to HIV prevention among Black MSM.

Additionally, the CBPR process led the HPTN 096 co-chairs to actively avoid colonial approaches that position Black communities as sites of risk and vulnerability that require external intervention and instead adopted a lens which recognized (a) the resilience and sociocultural assets that already exist in Black communities and (b) that HPTN 096 would be strengthened by working in partnership with Black-led national and southern region community organizers, such as the Black AIDS Institute and SBPAN, to achieve the study objectives. HPTN 096 is further institutionalizing the community engagement process through the intentional inclusion of Black MSM as members of the protocol team and by building two community engagement components into the infrastructure of the study design via the Community Strategies Group (CSG) and the Community Advisory Group (CAG).

(1) HPTN 096 CSG – The primary focus of this standing committee of the HPTN protocol team will be to develop and guide the community engagement activities for HPTN 096. In addition, this group will be the primary point of community input on HPTN 096 study design and components of the integrated strategy from a community perspective to inform the protocol writing and review process.

(2) HPTN 096 CAG – This will be the primary community advisory body for the study, active during pre-implementation and implementation periods, with broader representation from both intervention and control communities. The CAG will work directly with the CSG.

Community engagement in HPTN 096's integrated strategy builds on successful approaches in previous multi-level studies (50, 63, 87, 90). This integrated strategy seeks to strengthen partnerships between Black MSM, HCFs and local community stakeholders whose collaborative efforts will support implementation.

1.2.3 Critical Partnerships: CDC, HRSA, EHE Committees and Local Health Departments

As outlined in Section 1.1.2, the overall EHE strategy depends on the collaborative work of the CDC, HRSA, local health departments and EHE committees. In order for this study to work synergistically with these efforts, strong partnerships with these entities are critical. Key colleagues from Division of HIV/AIDS Prevention at the CDC and from both the Bureau of Primary Health Care and the HIV/AIDS Bureau at HRSA have helped design the study, are members of the protocol team and will continue to guide ramp-up and implementation activities. Specifically, the CDC will provide the aggregated data for the study endpoints that rely on HIV surveillance data (see Section 1.1.4). We have sought buy-in for community participation from all EHE committees, which are housed in local health departments, and include representation

from community-based organizations and HIV-related service facilities. The EHE committees and health departments are invited to serve as protocol team members, actively engage in our working groups if randomized to the intervention arm, work with the team to identify facilities for the intersectional stigma reduction intervention and potentially staff the baseline and post-implementation assessments.

1.2.4 Components of the Integrated Strategy

1.2.4.1 Health Equity

The current (and historically) observed differences in HIV incidence and clinical outcomes are not randomly distributed across the US population, but exhibit characteristics that are **systematic** (21, 91-93). These systematic differences often manifest in patterns of disease between social groups (e.g., Blacks compared to Whites; Straight vs Gay; southern states versus northern states). There are no biologically plausible explanations for why HIV infection rates would be consistently higher among Black people, MSM and Southerners compared to any other population or region in the US (94-97). These social patterns of disease are observed across multiple health domains, including Coronavirus Disease 2019 (COVID-19) case and mortality rates (98). The current state of the science is unequivocal that these health inequities are the product of structured social arrangements that assign underserved vulnerability and hardship (economic, social, legal) to one group while conferring unearned protections and benefits to another group (59, 99). The character and enforcement of these structured social arrangements, as well as their impacts on health inequities, may vary from one city to another (or from one region to another). Moreover, the interoperable systems that maintain structural inequities in health are not only "healthcare systems" but involve (1) multiple human social institutions such as education, law, employment and housing sectors (100-102) and (2) multiple processes of exclusion of communities from exercising self-determination over the material conditions of their lives (17, 103) . Therefore, approaches to promoting health equity (reducing unjust social gaps in disease rates and outcomes) must include approaches that extend beyond the healthcare sector to include education, legal, employment, civic and housing sectors and that are tailored to the realities affecting HIV prevention for Black MSM in their local community context (104, 105).

The current scientific evidence indicates that health equity interventions with the highest impact on reducing racial disparities in health involve local community mobilization that foster collaboration with governmental and non-governmental partners inside and outside of the health sectors (106-110). The patterns that characterize effective health equity interventions are principally (1) information sharing and exchange, (2) optimizing the impact of scarce resources through cooperation between partners and (3) actively working together in joint coordination to increase efficiency of access to services and resources (109, 111). One example of health equity intervention is an intersectoral partnership formed between community-based organizations, local health department, and academic institutions in Harlem, New York (112). This partnership identified HIV prevention as a shared priority and sought to reduce sharing and re-using of injection drug equipment by launching the Expanded Syringe Access Program (ESAP) coalition. The ESAP coalition cooperated on the development of materials describing the benefits of syringe exchange through dissemination of consistent messaging through their individual platforms (e.g., churches, community forums, drug counseling programs) in an effort to raise

awareness of ESAP among injecting drug users (IDUs), to sensitize the community to the needs of injection drug users and to reduce stigma (87, 112). The ESAP coalition developed a survival guide for substances users (information sharing) that included evidence-based health education guidance, a reference list of community services such as drug treatment, housing services and job placement services (87). The ESAP also developed and implemented a web-based resource for service providers (information exchange) that served as a database in which organizations could both update information on their available services as well as search to quickly identify externally available services for IDUs based on their needs and preferences. The efforts to increase efficiency of access to clean syringes was accomplished in coordination with local pharmacists who agreed to provide the non-prescription sale of syringes. The intersectional coalition resulted in a significant increase in their awareness of ESAP and decrease in the proportion of pharmacist with unsupportive attitudes about ESAP (87). Moreover, there was an increase in use of pharmacies for obtaining syringes among Black IDUs (22% v. 5%, $p<.02$) in the intervention community and no significant change in pharmacy use among Black IDUs in the comparison community (87).

These three characteristics (sharing, cooperating and coordinating) of successful health equity interventions are observed in other studies that range from an intervention that demonstrated evidence in increasing service engagement among MSM living with HIV through increasing community-level sensitization and acceptance in India (113) to an HIV prevention intervention in San Francisco that engaged gay bar owners to collaboratively provide free self-service access to water and used media inside their bars to share information encouraging the use of water to pace alcohol intake (114). The bars also coordinated an online networked platform in which patrons who used a breathalyzer could visualize their individual blood alcohol content (BAC) on an iPad alongside real-time comparisons to the average BAC of patrons in the bar as well as the average BACs of patrons in the other intervention bars (114). The health equity model in HPTN 096 is grounded in promoting principles of fairness and justice and is premised on the abundance of scientific evidence that local community coalitions and intersectoral collaborations are the most effective approach to tackling the enduring structural impediments driving HIV inequities among Black MSM in the South.

1.2.4.2 Social Media Influencers

Social Media Influencers (SMIs) are increasingly employed in a variety of fields to use the power of social media to reach large and diverse audiences. We will employ a combination of known and well established SMI practices and tools in HPTN 096, along with several innovations in use of these approaches. Innovative components will include the use of SMIs to address intersectional stigma for Black MSM.

The “diffusion of innovations model” suggests that behavior change in a population can be initiated and diffused to others if a behavior is visibly endorsed by enough natural and influential popular opinion leaders (POLs) within that population (115). Interventions that have identified (116) and trained POLs to disseminate HIV prevention messages through their social networks have successfully engaged vulnerable communities leading to adoption of prevention strategies including safer sex behaviors, HIV testing and PrEP uptake (117, 118). Further, a cultural adaptation of a POL intervention designed to promote the social normalization of condom use

and assist Black MSM in recognizing and handling risk-related racial and sexual bias, demonstrated significant reductions in HIV risk behaviors out to 12-months (119).

Coincident with the growth of digital technology, MSM increasingly utilize social media to obtain and engage with relevant sexual health information (120, 121). SMIs are users of social media with domain expertise who have established credibility, access to a large audience and can shape followers' attitudes and persuade them to act based on their recommendations (122). By constantly producing valuable content and cultivating reciprocal relationships with their followers (122), SMIs can facilitate engagement and receptivity of a brand (i.e. campaign message) by increasing its perceived authenticity, credibility and trustworthiness (123). Given their status as (micro-) celebrities, they can be a powerful resource for spreading campaign messages within communities. Further, SMIs can stimulate online conversations, introduce new information and ideas, and model healthy behaviors (124).

While there has been an explosion among health care providers, medical groups and pharmaceutical companies aiming to capitalize on the power and persuasion of SMIs to increase disease and drug awareness (125, 126), use of SMIs within public health to promote engagement in prevention behaviors is newly emerging. Findings from the Fresh Empire tobacco public education campaign suggest that SMIs can successfully disseminate tobacco prevention messages that resonate positively with their intended audience (127). Through collaborations with NIH, popular video bloggers and famous rappers, the STD AIDS Foundation in the Netherlands (*Beat the Macho* campaign) effectively engaged boys to challenge community norms on masculinity (128). With regard to HIV prevention, recent data from the COPE4YMSM study in Thailand provides evidence of the effectiveness of SMI to engage young MSM and young transgender women (aged 18-26) in a combination HIV preventive intervention (129).

1.2.4.3 Intersectional Stigma Reduction

The intersection of distinct stigmas (e.g., anti-Black racism, sexual stigmas, and HIV stigma), hereafter called intersectional stigma, produces a unique and synergistic effect on access and engagement in HIV prevention and treatment services. Racism is a system of structuring opportunity and distributing both privilege and disadvantage based on an individual's or community's assignment to social categories that are referred to as "races" (130). The system is multi-dimensional in that it operates at societal, institutional, interpersonal and intrapersonal levels (131-134). Racism is inherently anti-Black because it operates on a hierarchy where "whiteness" is assigned the highest value and "blackness" is assigned lowest value—while other groups experience benefit and/or disadvantage of racism based on their perceived social proximity to (and sometimes assignment to or revocation of) whiteness (135-137). Black MSM are subjected to anti-Black racism intertwined with HIV and sexual stigmas and this intersectional stigma can be experienced, perceived, anticipated and internalized. At the organizational (HCF) level, sexual stigmas (e.g. homophobia, heterosexism, gender non-conformity stigma) (138) are imposed on clients in a range of forms from verbal harassment (e.g. harsh, intrusive, unnecessary questioning) to unwillingness to provide care (or an attitudinal preference not to provide care) to MSM (67, 139). HIV stigma manifests globally in multiple forms ranging from verbal abuse to refusal to treat and avoidance behaviors like double gloving only with patients living with HIV; the latter driven by unwarranted fears of HIV transmission (140, 141).

Intersectional stigma is a significant barrier to engagement in the HIV prevention and treatment cascades. Intersectional stigma prevents Black MSM from seeking HIV testing and can undermine motivation for engaging in HIV prevention practices—such as PrEP use or treatment adherence that is critical for viral suppression among people living with HIV. The presence of intersectional stigma, including gossiping and a lack of supportive interpersonal disclosure, leads to guarded disclosures that are disruptive to HIV testing and early linkage to care (142, 143). Qualitative studies found sexual stigma undermines HIV testing for MSM and was a barrier to seeking general health and HIV treatment services (67, 144, 145). Within HCFs**,** negative interactions with staff can discourage MSM from seeking HIV testing or disrupt linkage to care (65). At the interpersonal and individual levels, perceived stigma can lead MSM to avoid health care services due to fear that someone will discover they have sex with men. Anticipated stigma can generate fear of potential discriminatory treatment at HCFs, which may lead MSM to avoid or delay accessing services (146, 147). At the individual level, internalized stigma may undermine motivation for engagement in HIV prevention and care activities and services (148).

The science of intersectional stigma is not yet mature and is currently characterized by a high level of exploration and innovation, driven partly by recent calls from the National Institute of Mental Health, National Institute of Nursing Research and the National Institute of Minority Health Disparities for more research on intersectional stigma reduction interventions to optimize HIV prevention and treatment outcomes (149). The current evidence-based stigma-reduction interventions in HCF only address one type of stigma such as HIV stigma, LGBT- stigma or mental illness stigma (150, 151). Nonetheless, there are key insights that can be learned from the current stigma-reduction interventions and applied to intersectional stigma-reduction interventions. Lessons can also be garnered from application of Quality Improvement (QI) approaches to reducing stigma and improving quality of care in HIV-related healthcare settings (152, 153).

A recent systematic review of HCF-based stigma reduction interventions identified six key approaches across the 42 studies reviewed: (1) providing core information about stigma manifestations and drivers, (2) skills-building activities that improve HCF workers abilities to work with stigmatized groups, (3) participatory learning, (4) facilitating contact with the stigmatized group by involving them in the intervention, (5) an empowerment approach that helps build resiliency among HCF clients and (6) structural or policy changes in the HCF (65). For example, in an HIV stigma-reduction intervention study conducted across four hospitals, whole-facility staff training, institutional policy development and capacity-building were used to significantly reduce both fear-based and social value-based HIV stigma (154). None of the studies in the systematic review addressed anti-Black racism with stigma; however, there is substantial literature on HCF-based racial disparities (110, 155-157). These interventions use many of the same approaches used in HCF-based stigma reduction. For example, the Accountability for Cancer Care through Undoing Racism & Equity (ACCURE) intervention eliminated post-intervention racial disparities in cancer screenings (158). The intervention included the provision of foundational information on structural racism, participation in a historical analysis of how race and racism operate across sectors of society; however, the ACCURE intervention went beyond “facilitating contact” with stigmatized groups and worked in sustained collaboration with a local community coalition to examine the institutional practices

and policies of the HCF (158, 159). The ACCURE project also included skills-building through an electronic health record-based audit and feedback procedure, and structural change through the implementation of a nurse navigator trained to use a racial equity lens in identifying and responding to patient's needs (158). Audit and feedback approaches have been used in other interventions to reduce racial disparities (157), although there are very few that have integrated contact with stigmatized patient with audit/feedback into one cohesive approach (160). HPTN 096 will contribute to advancing the knowledge about HCF-based intersectional stigma reduction for HIV prevention through the implementation of key approaches that have been shown to reduce the prevalence and intensity of stigma in HCFs and integrate them with approaches shown to be effective at addressing institutional racism and its negative impacts on health care service use and health outcomes.

While not the only element, the provision of intensive, participatory, skills-based training has emerged as an integral piece of comprehensive and effective stigma (including intersectional stigma) reduction interventions in HCFs (65, 161). Current stigma reduction approaches can provide important insights into the dose and training approach that may be most useful in successfully shifting attitudes and skills towards a more culturally responsive healthcare environment for Black MSM in a way that will lead to meaningful change.

Adult learning theories can inform the training approach. Transformative learning theory and Miller's pyramid provide useful frameworks (162). Knowledge transfer is the foundation of Miller's pyramid, "but not the pyramid itself" – the intent is to convert knowledge into action (162). Transformative learning theory posits that learners must consider new knowledge to critically reflect on beliefs and assumptions and move through a process to ultimately restructure their perspectives (163). Both the research-derived and practice-derived evidence bases on training methods are conclusive that transformation to awareness and understanding of these biases and how they impact on clinical encounters, environments and outcomes, as well as mastery of skills and strategies to overcome them, cannot occur through brief, didactic provision of information in the way that typical clinical competencies may be taught (164).

There exists a precedent for an intensive workshop approach to address stigma-reduction in HCFs. For example, the Health Policy Project, a global HIV stigma reduction program funded by USAID, published an extensive training guide describing a modular training program with prescribed content that can be flexibly implemented, and recommended that a base training program be a whole facility approach (training all staff) over a minimum of a 2-days (165). Nyblade et al. describe elements of successful stigma reduction programs, including one in Vietnam that involved a participatory multi-day training (161). A systematic review of HIV stigma reduction interventions describes the majority as skills-building and delivered over multiple sessions and over the course of many hours or days (166). Likewise, within the arena of anti-racism training, many popular models (such as The People's Institute for Survival and Beyond Undoing Racism Workshop TM, the Racial Equity Institute, and the National Conference for Community and Justice's Dismantling Racism Institute) are multi-day immersive, transformative learning workshops. The Aspen Institute's guide to Training for Racial Equity and Inclusion highlights these programs and recognizes time and financial constraints as challenges to be overcome in implementing this kind of workshop approach in order to effectively address the multi-dimensional facets of racism and implicit bias to achieve

long-term outcomes (167). The successful ACCURE project utilized Undoing Racism as a cornerstone of their HCF-level intervention (168). While feasibility is an important consideration, changing complex organizational- and healthcare worker-level psychosocial processes and behaviors requires complex training modalities.

1.2.4.4 Peer Support

Peer support programs in various forms have been an important intervention for Black MSM in both preventing HIV and maintaining HIV care and treatment adherence. A recent study focused on acceptability of peer navigators among Black, Brown and other MSM of color in navigating PrEP and HIV testing showed overwhelming openness to peer interventions, particularly if peers were of the same sexual orientation or racial identity (169). Studies have shown that effective peer support and social networks can serve to increase PrEP education and trust, and to also help overcome PrEP stigma and mistrust that are contributing to PrEP disparities for Black MSM. This study points to the potential role of peers to increase PrEP uptake in this population (107). Several studies have shown that peer support, whether with peer outreach workers proficient in motivational interviewing or other Black MSM within social networks, is associated with higher rates of HIV testing and a reduction in HIV risk behavior (119, 170). For example, Project HOPE (Harnessing Online Peer Education), an online peer health education intervention using social media tools for HIV prevention led to increased HIV testing rates among young Black MSM (171). The use of technology in delivering peer support interventions, including through text messaging or through the use of other virtual platforms, has been proven effective for Black MSM in HIV care engagement (172).

A recent global meta-analysis of peer interventions for people living with HIV confirmed an overall trend towards increased linkage and retention (173). The CDC has endorsed multiple peer support interventions for people living with HIV, which have been shown to increase HIV care engagement and treatment adherence (174), and in turn reduce risk of transmission to uninfected partners. Successful evidence-informed community-based peer interventions specifically focused on Black MSM, including d-up: Defend Yourself! and STYLE (Strength Through Livin' Empowered), have shown promising outcomes along the HIV care continuum (175, 176).

1.2.5 Theoretical Premise for Integrated Strategies

The design of this study is informed by the network-individual-resource (NIR) model of HIV prevention with components integrated from self-determination theory (SDT) (177). The NIR model is one recent innovation in HIV prevention theory development that takes into account the influence of communities, institutional systems and close others (e.g., peers, families) on an individual's agency (i.e., motivation to act and capacity to act) for enactment of behaviors that contribute to HIV prevention (e.g., PrEP use and HIV treatment adherence) (177). This model also proposes that peers can affect health through social support, social behavioral regulation, and facilitating access to resources. In the NIR model both mental and tangible resources must be engaged in order to optimize HIV prevention (177). Tangible resources are assets that structure conditions that facilitate healthy behaviors. Mental resources refer to the psychosocial characteristics of people and networks that serve as assets for the avoidance of HIV/STI risk behaviors. In this study, we used NIR to guide the selection of integrated strategy components that serve as assets that have a positive influence at the community (SMIs), organizational

(increasing culturally responsive care in HCFs) and interpersonal (peer social support) levels, as well tangible resources at the community (health equity promotion), organizational (reducing intersectional stigma as access barriers in healthcare facilities), and interpersonal (decentralized virtual access to peer support) levels.

SDT is a social psychological theory of human motivation that contends that healthy behavior change is optimized in environments that support humans' basic psychological needs for autonomy (freedom from control), competence (acquisition of skills and resources needed to master goal attainment), and relatedness (authentic connection) (178). In this study, SDT concepts of autonomy, competence, and relatedness are integrated into the NIR model by operationalizing them as qualities of the psychosocial assets operating within the HCF and virtual peer support environments to facilitate PrEP use, HIV testing and HIV treatment adherence among Black MSM. SDT concepts are further integrated by operationalizing them as qualities of tangible resources that support autonomy and competence at the community level (addressing local community-identified priority issues impeding PrEP use, testing and viral suppression) and competence support at the organizational (increasing proportion of HCF staff trained in culturally responsive approaches to care) and interpersonal (increased access to support with navigating health system and identifying resources) levels. It is also important to distinguish "independence" from the concept of "autonomy" as defined in SDT. Independence is the exercise of thought or action without external input. This is different from autonomy that involves the experience of one's actions as fully willing and without external controls, while accommodating the input and influence of important others such as SMIs, healthcare providers and peers (179). Moreover, as demonstrated in studies across various cultural contexts—including US, Brazil, Canada, China, Ghana, India, Nigeria, Russia and Ukraine—SDT is similar to the local community coalition approach that characterizes the health equity component of HPTN 096, in that SDT does not presume "independence" in decision-making (180-184). Decisions and/or behaviors that are derived from collective-centered thought can still be experienced as willful and volitional (not forced) with those involved assenting to act "together" or in the interest of the group. SDT accommodates the reality that, for many MSM in Black communities across the American South, even while behaviors are expressed at the individual-level, antecedent psychosocial processes and social/structural determinants are at times influenced at the group or community-level.

2.0 STUDY OBJECTIVES AND ENDPOINTS

The overall goal of this study is to decrease HIV incidence in Black MSM in the southern US by increasing HIV testing, PrEP uptake and viral suppression in the intervention communities. The primary and secondary objectives reflect this goal, using a mix of study-collected data and routinely collected HIV surveillance data. Commercially available PrEP prescription data will also be used in supportive analysis. HIV surveillance data are collected continuously by the CDC via local health departments and prescription data are updated on a quarterly basis. There is no central database that captures all PrEP prescriptions and includes both race and risk. At this point in time, commercial prescription databases exist, which include a subset of prescriptions, and attempts are being made to collect race information. The protocol team will use the PrEP prescription databases currently available in supportive analysis (e.g., Symphony Health or IQVIA being purchased by the CDC and/or AIDSVu) and will use Black men as a proxy for

Black MSM. If over the course of the study a more complete PrEP prescription database that includes risk and race emerges, the protocol team will consider modifying the current PrEP prescription data source.

While the parameters of PrEP uptake and viral suppression are captured in the primary objectives, increases in HIV testing are not. This is because there is no systematic way that overall HIV testing is collected in US. Although subsets can be captured via funders (e.g., CDC-funded tests) or testing laboratories (e.g., private laboratory testing databases), these do not represent an overall picture, and more importantly, they do not systematically report data that includes race and risk. HIV surveillance data does capture new HIV diagnoses, but this is not a direct measure of HIV testing uptake. Because HIV testing is a critical element in the pathway of decreasing HIV incidence, self-reported HIV testing is included as a secondary objective measured through the cross-sectional assessments. If over the course of the study an HIV testing database that includes risk and race emerges, the protocol team will consider adding an objective to the study.

2.1 Primary Objectives

The primary objectives of this study are:

2.1.1 To increase the proportion of Black MSM living with diagnosed HIV who are virally suppressed (<200 copies/mL) in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on HIV surveillance data

2.1.2 To increase PrEP use by Black MSM not living with HIV in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment

2.2 Secondary Objectives

The secondary objectives of this study are:

2.2.1 To compare self-reported HIV testing behavior in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on the post-implementation cross-sectional assessment

2.2.2 To compare social support, intersectional stigma, barriers to healthcare, and individual agency in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on the post-implementation cross-sectional assessment

2.2.3 To increase the proportion of Black MSM living with HIV newly diagnosed in the past year who are virally suppressed (<200 copies/mL) within six months of diagnosis in the intervention communities compared to the SOC communities at the end of the three-year integrated strategy based on HIV surveillance data

2.2.4 To track ongoing EHE implementation activities for Black MSM (e.g., outlined by the EHE plans) of both intervention and control communities (used for adjustment in analyses and to assess implementation outcomes of acceptability/compatibility)

2.2.5 To assess measures of care quality, and care responsiveness to Black MSM needs at HCFs participating in the Culturally Responsive Intersectional Stigma Prevention (CRISP) component, pre- and post-implementation (used to assess service outcomes)

2.3 Exploratory Objectives

The exploratory objectives of this study are:

2.3.1 To compare the estimated HIV incidence in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment

2.3.2 To compare use of antiretroviral drugs by Black MSM living with HIV in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment (this analysis will be limited to a subset of communities)

2.3.3 To compare HIV drug resistance in Black MSM living with HIV in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on laboratory data generated from the post-implementation cross-sectional assessment (this analysis will be limited to a subset of communities)

2.3.4 To use mathematical modeling to

- inform interim analysis by using HIV surveillance data on viral suppression during the trial to predict the expected impact on HIV incidence at the end of the trial
- estimate the longer-term impact of the integrated strategy on HIV incidence among Black MSM in the southern US
- estimate the contribution to the overall impact on HIV incidence made by each of the integrated strategy components

2.3.5 Using attribution analysis, estimate the contribution made by each of the integrated strategy components (health equity, social influencers, intersectional stigma reduction, and peer support) to changes in viral suppression and PrEP use among Black MSM in the southern US

2.3.6 Stored specimens may be used for laboratory assessments that include phylogenetic analysis of HIV in the study communities; characterization of HIV; development, validation, evaluation of laboratory assays relevant to the HIV epidemic and study objectives, and testing associated with SARS-CoV-2 and other related viruses

2.4 Endpoints and Data Sources for Primary and Secondary Objectives

Table 2 below presents the endpoints and data sources for each objective.

Table 2. Map of HPTN 096 Objectives to Endpoints and Source of Evaluation Data

Objective (Summary)	Endpoints	Data Source
Primary Objectives		
2.1.1 Viral suppression in Black MSM living with diagnosed HIV	• (primary) The ratio of the number of Black MSM living with diagnosed HIV who are virally suppressed (<200 copies/mL) as measured by HIV surveillance data divided by the number of Black MSM living with diagnosed HIV as measured by HIV surveillance data • (supportive) HIV viral load measured in the cross-sectional assessments	National HIV Surveillance System Data from CDC For supportive analysis: Cross-sectional laboratory assessment (plasma HIV viral load)
2.1.2 PrEP use by Black MSM not living with HIV	• (primary) The presence of PrEP agents measured in a dried blood spot (DBS) collected during the cross-sectional assessments • (supportive) The ratio of the number of Black men with PrEP prescriptions (from AIDSVu) divided by the number of Black men with PrEP indications (from CDC)	Cross-sectional laboratory assessment (DBS) For supportive analysis: commercially available PrEP prescription data from AIDSVu/CDC and PrEP indication data from the CDC
Secondary Objectives		
2.2.1 Self-reported HIV Testing behavior in Black MSM	Responses to survey questions collected during the post implementation cross-sectional assessment	Post-implementation cross-sectional questionnaire
2.2.2 Social support, intersectional stigma, barriers to healthcare, and individual agency in Black MSM	Responses to survey questions collected during the post-implementation cross-sectional assessment	Post-implementation cross-sectional questionnaire
2.2.3 Viral suppression within 6 months of new diagnosis in Black MSM living with HIV	The ratio of the number of Black MSM with HIV newly diagnosed in Year 3 who have a suppressed viral load (VL) within six months of diagnosis as measured by HIV surveillance data divided by the number of Black MSM with HIV newly diagnosed in Year 3 based on HIV surveillance data	National HIV Surveillance System Data from CDC

Objective (Summary)	Endpoints	Data Source
2.2.4 Tracking EHE implementation activities for Black MSM	Information about EHE implementation activities affecting Black MSM in the EHE plans of all intervention and control communities, as well as additional information from local health departments and EHE committees	EHE plans of intervention and control communities, as well as additional information from local health departments and EHE committees
2.2.5 Care quality and responsiveness to Black MSM needs at HCFs participating in CRISP	• Self-reported survey data from health care workers who participate in the CRISP component • Aggregated, facility-level independent ratings of HCF workers • Self-reported survey data from Black MSM receiving services at HCFs participating in CRISP activities	• Surveys of health care workers who participate in CRISP component • Ratings by independent raters • Surveys of Black MSM receiving services at CRISP health care facilities

3.0 OVERVIEW OF STUDY DESIGN

HPTN 096 is a community-randomized, controlled, hybrid type III implementation effectiveness study focused on Black MSM in selected EHE communities in the US South (See Schema Figure 1 for an overview of the study design). HPTN 096 is a four component, multi-level integrated strategy. The four components of the integrated strategy include: 1) a health equity component using a community coalition model as a basis; 2) use of SMIs to raise awareness, reduce stigma, increase motivation for positive health behaviors, and inform Black MSM of available health and other relevant services within their communities; 3) an intersectional stigma reduction component aimed at HCFs and staff; and 4) virtual peer support for HIV/STI testing, PrEP and HIV prevention, ART initiation and ongoing adherence, and provision of information about access/assistance programs. These four components will be implemented over the course of three years (after a one-year ramp-up period). The goal of this study is to capture both the short and long-term term impact and sustainability of the integrated strategy. It is expected that it will take substantial time for the components to diffuse – spread and take hold – within the entire community to the degree that would allow the effects to be observable in a cross-sectional endpoint assessment. This assumption is supported by Hallett and colleagues who postulate that "HIV prevention interventions, especially those targeted at high-risk groups may take longer to work at the population level and need more follow-up time in a CRCT to generate statistically significant results" (185). Although we plan to begin the study when the full integrated strategy is functional within the communities, we expect there to be a substantial change over time with regard to the number of people who know about and benefit from specific components of the implementation strategy (peer support), for attitudinal changes to take place (social media influencers and intersectional stigma reduction) and for changes in policies and practices to be made (health equity). Modeling data from Boily and colleagues support this approach, estimating that it will take 3-4 years for multi-component interventions to have optimal impact on HIV incidence (186).

The study seeks to reduce new HIV infections among Black MSM by increasing rates of HIV testing, increasing rates of viral suppression among Black MSM living with HIV infection, and by increasing PrEP uptake, adherence and persistence among Black MSM at risk for HIV infection. Application of a model previously developed for HPTN 078 suggests (188) that a 10 percentage point increase in viral load suppression and 15 percentage point increases in PrEP uptake (assuming good adherence) would lead to a 35% relative decrease in HIV incidence. These results are, of course, dependent on model assumptions, but are calibrated to current data on viral suppression and PrEP uptake. Also, the model suggests that if the additional PrEP reaches those at higher risk, the impact on HIV incidence would be greater. This analysis suggests that our target intervention effects on viral suppression and PrEP uptake, when combined, are predicted to have a meaningful impact on HIV incidence in Black MSM.

The study will randomize eight matched pairs of EHE communities; 16 communities will participate overall, which have been selected from the 28 EHE counties and Washington, DC, and six high burden rural EHE states in the South. The selected EHE "hotspots" were based on high burdens of HIV prevalence and on recent HIV diagnoses. Pair selection and matching has been done on an epidemiologic basis, using CDC surveillance and other available data on demographics, geographic distance, HIV burdens in men, MSM, and Black MSM and viral suppression in Black MSM. While imperfect, other studies suggest that the great majority of Black men on PrEP are MSM, which is also the case for men of other races and ethnicities using PrEP. As is generally true of community randomized designs, there is no blinding scheme in this study.

The baseline assessment is smaller than the final post-implementation assessment, sampling 100 men in each community (approximately 1600 in total across the arms) while the post-implementation assessment will include approximately 200 men per community, 3,200 in total. Because a population-based sampling frame with a known denominator is not possible for this hidden and marginalized population, and actual denominators cannot be known, the study will use a recently developed sampling approach, starfish sampling, which utilizes the principles of both venue-time sampling and respondent-driven sampling, the two available strategies often used to reach Black MSM (187).

The design uses endpoints from CDC surveillance, commercially available prescription data, as well as cross-sectional data collected at baseline and at the end of implementation of the three-year integrated strategy in each intervention and control community. The two co-primary endpoints are derived from different sources. The first endpoint is rates of viral suppression in each community among diagnosed Black MSM living with HIV infection and alive at the end of each study year, data made available by a partnership with the CDC through their HIV surveillance reporting systems. Since the CDC will be collecting and reporting on these data in each year of the study, data on rates of viral suppression among Black MSM in each intervention and control community will be used in years one, two and three (the final year). The second co-primary endpoint will be the proportion of Black MSM in each community on PrEP, which will be assessed at baseline and post-implementation assessments through biological specimen collection. Both primary objectives will use additional data for supportive analysis (see Table 2).

During the study, periodic review of interim CDC surveillance viral suppression data, interim PrEP prescription data, and the study process measures outlined for each component will be conducted to assess progress; if needed, implementation will be adjusted accordingly. A key exploratory endpoint will be an assessment of the rate of recent HIV infection in intervention vs control communities, which will be assessed with biological specimen collection at baseline and post-implementation.

The study will be sponsored by the NIH but will be a collaboration with the other two main federal agencies tasked with implementing EHE: the CDC (for surveillance) and HRSA (for clinical care). It will also include a range of Black community partner organizations, and the EHE planning councils that have been established in each of the EHE jurisdictions.

3.1 Study Duration

Study duration is approximately 6 years total, which includes a one-year ramp up period prior to the start of the 3-year study implementation period. Based on the Network's experience with previous integrated strategies and individual studies (e.g., HPTN 071, HPTN 065 and HPTN 078), at least 36 months are required to measure the impact of such a large, community-wide strategy. The cross-sectional assessments will be conducted prior to and immediately following implementation of the 3-year integrated strategy. Each assessment will take approximately 6 months to complete, and the baseline assessment will take place during the ramp-up period. The ramp-up period may take less than one year, if all ramp-up activities and the baseline assessment are complete sooner than expected; the implementation period will begin as soon as the ramp-up period is complete. Laboratory testing, data analysis, and analysis of surveillance data will require approximately 1.5 years after completion of the post-implementation assessment. No individual participants will be followed on study.

4.0 STUDY POPULATION

4.1 Description and Selection of the 16 Study Communities

The potential universe of communities for this study includes those of highest HIV burden within the Southern US as identified by the EHE plan. Specifically, this includes Washington DC, 23 counties within Florida, Georgia, Louisiana, Maryland, North Carolina, Tennessee, and Texas, as well as counties within the six rural states of Alabama, Arkansas, Kentucky, Mississippi, South Carolina, and Oklahoma. Each community will be made up of one to four counties, taking into account contiguous and non-contiguous counties where the Black MSM population lives, works and socializes. These communities will be the "randomizable units" for the study. Eight matched pairs of communities will be chosen based on several criteria that require each pair to:

- Be geographically distinct (at least 120 miles apart from one another)
- Include proximal counties where Black MSM frequently travel
- Have roughly equivalent populations (overall, male, Black male)
- Have roughly equivalent (target of +/- 35%) HIV prevalence for Black men
- Share similar rates (target of +/- 30%) of viral suppression for Black MSM

The possible communities, as defined by the study team, are listed in Table 3 and shown in Figure 4. Note that the number of Black MSM living with HIV in Oklahoma and Kentucky is very small and not concentrated in one location. This fact raised concerns regarding the potential ability for the integrated strategy to reach such a small and non-localized population, as well as the feasibility of conducting a cross-sectional assessment successfully. Thus, no locations in Oklahoma or Kentucky will be considered for study participation.

Figure 4: Map of Potential Communities for Study Participation

Table 3: List of Potential Communities for Study Participation

Community	State	County
Birmingham	AL	Jefferson County
		Shelby County
		Tuscaloosa County
Mobile	AL	Mobile County
		Baldwin County
	MS	Jackson County
Montgomery	AL	Montgomery County
		Elmore County
		Autauga County
Little Rock	AR	Faulkner County
		Jefferson County
		Pulaski County
DC/MD suburbs	DC	Washington DC
	MD	Montgomery County
		Prince George's County
Jacksonville	FL	Duval County
Ft. Lauderdale	FL	Broward County
Orlando	FL	Orange County
Tampa/St. Petersburg	FL	Pinellas County
		Hillsborough County
Atlanta	GA	Cobb County
		DeKalb County
		Fulton County
		Gwinnett County
Baton Rouge/New Orleans	LA	East Baton Rouge Parish
		Orleans Parish
		Jefferson Parish*
Baltimore	MD	Baltimore City County
Jackson	MS	Hinds County
		Madison County
		Rankin County
Charlotte	NC	Mecklenburg County
Charleston	SC	Charleston County
		Dorchester County
		Berkeley County
Columbia	SC	Lexington County
		Richland County
		Sumter County
Greenville	SC	Greenville County
		Spartanburg County
Memphis	TN	Shelby County
Dallas	TX	Dallas County
		Tarrant County
Houston	TX	Harris County

*This is not an EHE identified jurisdiction; however, it is contiguous with Orleans Parish and is part of the overall New Orleans community where Black MSM live, work and socialize.

4.2 Randomization

Prior to randomization, communities will be paired based on demographics (community size and percent of the population that are Black) and baseline rates of viral suppression (based on CDC data). Within each pair, one community will be randomized to receive the integrated strategy components and one will be randomized to the SOC. Randomization will take place in a public ceremony.

4.3 Priority Population for Components of the Integrated Strategy

The primary population being prioritized for this study comprises all Black MSM in the participating intervention communities within the southern US, regardless of HIV status. However, populations that will participate in each component of the integrated strategy may extend beyond this population, and each component may target additional populations. The following study populations will be prioritized for each component of the integrated strategy:

- **Health Equity:** Black MSM and local community
- **Social Media Influencers:** Black MSM
- **Intersectional Stigma Reduction:** Healthcare facility staff
- **Virtual Peer Support:** Black MSM

Any specific inclusion or exclusion criteria for each component of the integrated strategy are listed in the specific component Sections below.

4.4 Priority Population for Cross-Sectional Assessments

The baseline and post-implementation cross-sectional assessments will include Black MSM in both the intervention and control communities. The specific inclusion and exclusion criteria are listed in Section 10 (Cross-Sectional Assessments).

5.0 HEALTH EQUITY COMPONENT

5.1 Hypothesis

Implementing a standardized, nationally replicable community coalition model will contribute to the reduction of HIV incidence among Black MSM in intervention communities by:

1) Facilitating the effects of the other HPTN 096 components of the integrated strategy by minimizing barriers to HIV testing, PrEP use and viral suppression through sensitizing a local network of service providers (e.g., social, legal, economic sectors) to the needs of Black MSM and maintaining an online platform for exchanging information about the local network that can be used to link Black MSM to resources and services.

2) Amplifying the effects of the other HPTN 096 components of the integrated strategy by increasing the Black MSM's receptivity to those interventions through the integration and promotion of HPTN 096 into the activities of the community coalition model.

5.2 Component Description

The health equity component will use a community coalition program as its base model for shaping community social norms within the local service sectors to be supportive of wide-scale adoption of HIV testing, PrEP use and treatment engagement to reduce HIV inequities among Black MSM. The community coalition program will be implemented through the BTAN as the base model for the health equity intervention. The Black Treatment Advocates Network (BTAN)—an existing program of the Black AIDS Institute (BAI)—is a national network of HIV stakeholders including service providers, community members and leaders, educators, and people living with HIV who mobilize Black communities to confront HIV. The national BTAN is comprised of community coalitions across the country that are locally organized, but centrally supported with administrative and technical assistance by the BAI. Local coalitions that maintain a minimum number of members and agree to implement the BTAN's standard training and program activities are designated as "chapters" (see Section 5.2.4). Chapters serve to unify and magnify the work of Black communities. Coalitions that do not meet the minimum membership threshold or who do not implement the standard program activities are designated as "affiliates"; however, as described further in Section 5.2.4, HPTN 096 will strive to implement the health equity component through local coalitions that are designated as BTAN chapters, specifically.

As the BTAN is an existing national network of HIV stakeholders, existing BTAN chapters in communities randomized to the intervention arm of the study will be engaged as implementers of this study. In intervention communities that do not have an active BTAN chapter, BAI will establish new BTAN chapters so that there is at least one in each intervention community. The standard BTAN chapter model consists of three domains (education, leadership development and community mobilization) from which all BTAN activities are derived. The health equity intervention BTAN chapters (defined as those BTANs – new or existing - in each HPTN 096 intervention community) will be referred to as BTAN*Plus* (+) chapters to designate that, in HPTN 096, BTAN+ chapters will implement enhanced activities above and beyond their standard chapter activities across the three domains (see Section 5.3 for component activities). The engagement/establishment of BTAN+ chapters in each intervention community implementing this enhanced operating model will comprise the health equity component of this study.

The BTAN+ chapter enhanced operating model will impact the study outcomes through two strategy pathways: facilitation and amplification (57). BTAN+ chapters will facilitate the effects of the other HPTN 096 components by promoting norms within the local service sectors (e.g., social, legal, economic) that support the strategic prioritization of access to resources and services for Black MSM that can minimize barriers to HIV testing, PrEP use and viral suppression. BTAN+ chapters will amplify the effect of the other HPTN 096 components through the integration and promotion of HPTN 096 into its community mobilization activities, thereby increasing Black MSM's receptivity to the use of HIV testing, PrEP and other HIV prevention services, ART, and virtual peer support. Section 5.3 further details the specific activities that are expected to facilitate these strategy pathways.

5.2.1 Integration of BTAN+ Chapters within the Existing BTAN Network

As previously noted, BTAN chapters or affiliates already exist in communities across the nation, some of which may be randomized to the SOC arm of the study. Existing BTAN chapters in communities randomized to the intervention arm will be transitioned to the BTAN+ chapter operating model; one key defining characteristic of this model is the careful and distinct prioritization of Black MSM in all facets of the chapter activities, which is not a defining characteristic of the existing standard BTAN operating model. Existing BTAN chapters in SOC communities will not be offered the opportunity to implement the BTAN+ chapter program model and will be expected to continue their normal operations. If an existing BTAN chapter is at the state-level, a new local-level BTAN+ chapter will be established for the intervention community, and the state-level BTAN chapter will continue under the standard operating model (see Section 5.2.4).

In order to prevent issues of inequity and potential harm that a differential operating model may cause within the existing BTAN network and with BAI, and in order to preserve the strength of BTAN chapters that is derived from being part of this national network, BTAN+ chapters (existing and new) will continue to participate in all national-level BTAN activities and convenings (e.g., monthly all-BTAN leadership calls). Additionally, the core leadership of all BTANs/BTAN+ chapters within SOC and intervention communities will be compensated for their leadership efforts (see Section 5.4.3). However, BTAN+ chapters will also participate in additive, HPTN 096-only activities and convenings, such as monthly leadership and/or technical assistance calls with BTAN+ chapter leaders only and may be offered the opportunity to participate in other BTAN+ chapter trainings. This will provide an opportunity for BAI administration of BTAN+ chapters to focus specifically on integrated strategy-related items and activities, while not precluding these intervention community chapters from being actively engaged in the broader national BTAN network. BTAN chapter members from both SOC and intervention communities will undergo education and training around the concept of the HPTN 096 study, the community randomized design, and BAI/BTAN's role in this study. Additionally, indicators of contamination will be captured as part of the process measures for this component (see Section 5.5). While these measures combined will not entirely remove any possibility for contamination between SOC and intervention community BTAN chapters, they will mitigate this risk as much as can be controlled by the study team and BAI while still preserving the integrity and functioning of the existing national organization.

5.2.2 Implementers

The health equity component will be implemented by local BTAN+ chapter leadership and members, administered and overseen by BAI, and in partnership with other community-based organizations in the intervention communities. BAI will be responsible for establishing and/or maintaining BTAN+ chapters in all intervention communities and ensuring the BTAN+ chapters are fully supported to implement the enhanced operating model (see Section 5.3). Local BTAN+ chapters' leaderships are also responsible for ensuring their BTAN+ chapter follows the enhanced operating model. Where beneficial, BTAN+ chapters will work in partnership with existing community-based organizations (particularly those that are led by and for Black MSM and Black communities) that have similar goals and objectives (see Section 5.3.1).

5.2.3 Location

At least one local BTAN+ chapter will be established in each intervention community. Local BTAN+ chapter leadership will determine the meeting location for their chapter within the intervention community, and if preferable or necessary, may meet virtually. In-person chapter activities may take place at any location deemed suitable within the boundaries of the intervention community.

5.2.4 BTAN+ Chapter Definitions

Each BTAN+ coalition will be supported to achieve and maintain BAI requirements for official chapter status. To meet these requirements, BTAN+ groups must:

- Have at least 20 members (defined as the individuals registered with the chapter at each assessment period);
- Have regular monthly meetings;
- Have leadership comprised of a chair and co-chair; and
- Participate in regular all-BTAN leadership calls.

Additionally, BTAN+ chapters must be comprised of members and organizations located solely within the geographic bounds of an HPTN 096 intervention community. State-level BTAN chapters may not operate as BTAN+ chapters. In the case of pre-existing state-level BTAN, new BTAN+ chapters will be established that are limited to the confines of the intervention community.

BTAN+ coalitions will have the goal of achieving chapter status by at least the first year of study implementation and maintaining that status with BAI over the 3-year study implementation period. BAI will assess the status of each BTAN+ chapter at least twice yearly. In the situation where a BTAN+ coalition falls below chapter status, BAI will work closely with the group to understand challenges preventing the achievement or maintenance of chapter status, and to make adjustments as necessary to increase the engagement and/or membership of the group in order to achieve chapter status.

5.3 Health Equity Component Activities

5.3.1 Formative Work

In many HPTN 096 communities, it is likely that at least some efforts are already ongoing by grassroots community organizations for Black MSM with similar goals as this study. Prior to establishing the local BTAN+ chapters and implementing this component of the integrated strategy, formative work will take place during the pre-implementation and ramp-up periods to better understand the existing community structures and organizations in each intervention community that are currently operating within the HIV field and/or doing work related to Black MSM. Formative work will also take place to describe the make-up and dynamics of any existing BTAN chapters in HPTN 096 communities. Attempts will be made to engage with these existing

organizations and foster partnerships with and between them, for example through involving them as members in the BTAN+ chapters, partnering with them for BTAN+ activities, or seeking their expertise in planning of the BTAN+ chapters' community efforts and activities. The goal of this formative work will be to understand the existing Black MSM community coalition landscape and seek to further potentiate it through combined efforts rather than competition. In some cases where BTAN chapters do not currently exist in intervention communities, these already-active organizations may form the foundation of the new BTAN+ chapter, and BTAN+ chapters (new or existing) may bring in additional membership from these organizations. In this way, a synergy will be formed between various organizations working on the ground towards common goals related to health and social welfare of Black MSM. These partnerships will serve to broaden the local BTAN+ coalition and further strengthen the reach and capacity of BTAN+ in each community.

5.3.2 Facilitation Component

The first step in promoting multi-sector norms in which organizations/programs leverage their services (e.g., medico-legal, social services, housing, addiction, mental health, food security) to support reducing HIV among Black MSM will be for BTAN+ chapter members to participate in the CRISP intervention Foundation Training (see Section 7.0) and complete four hours of training on structural competency as part of their BTAN+ chapter training. Structural competency is the understanding of how the health of individuals is influenced by upstream factors across multiple sectors (189-191). BTAN+ chapter members will be trained in structural competency by the HPTN 096 study team using an open source curriculum (192) and a train-the-trainer approach that will allow BTAN+ chapters to provide training periodically for new members who join the chapter. After a BTAN+ chapter completes these trainings, it will then conduct a rapid mapping of local community resources. BTAN+ chapters will be supported and trained by the HPTN 096 study team to conduct a community resources mapping exercise (193, 194). BTAN+ chapters will identify local services and resources that address social determinants, convene an equity forum (or forums) to raise awareness among the identified organizations of the goals of EHE and HPTN 096 and secure their cooperation to support these goals by finding ways to prioritize the service needs of Black MSM. These equity forums will include brief presentations of research evidence and case examples to illustrate the ways in which their services can be harnessed to help alleviate hardships experienced by Black MSM that, if unaddressed, can undermine HIV prevention and EHE goals. For example, agencies offering pro bono legal services can assist in alleviating an economic hardship by assisting an eligible individual to apply for and/or appeal unemployment benefits, which may be key for him being able to afford food and utilities needed to maintain his adherence to ART. Equity forums together with the BTAN+ chapters will identify barriers to Black MSM accessing services and collaboratively discuss ways to address these barriers. BTAN+ chapters may then look for additional community-driven solutions where possible.

As a follow-up to the equity forums, curated rosters of services, agencies, and individuals willing to provide these services will be compiled and maintained by the local BTAN+ chapters. The curated roster will be publicly accessible via a website maintained by BAI and serve as a referral tool that can be used by HPTN 096 peer supporters, HPTN 096 SMIs, staff at CRISP HCFs and/or directly by Black MSM for self-referrals. This approach integrates the activities of the BTAN+ chapters, SMIs, peers and CRISP-trained HCFs in a coordinated manner that will

expand Black MSM's awareness of services across multiple sectors in the intervention communities. Equity forums are expected to continue periodically over the course of the 3-year intervention period to facilitate sustained engagement with and sensitization of these multi-sector service providers.

5.3.3 Amplification Component

BTAN+ chapters will amplify the effects of the other HPTN 096 activities via increasing Black MSM's receptivity to those components by increasing efforts within the chapter that are focused on HIV testing, PrEP use, and viral suppression in Black MSM. This will include, for example, amplifying prevention messages (from public health sources and potentially from SMIs) or by integrating content endorsing virtual peer support, local HIV/STI testing and/or the range and availability of options for HIV PrEP and ART into their programming and communications strategies. Amplification activities could also involve the dissemination of information that links Black MSM directly to HPTN 096 integrated strategy components, including directing them to the local BTAN+ chapter website where they can access a list of HCFs participating in the CRISP intervention (those HCFs that agree to be listed on the website), the rosters of available local resources cooperating to support HIV prevention needs of Black MSM and instructions on how to access virtual peer support.

5.3.4 BTAN Chapters: Standard versus Enhanced Activities

Table 4 below displays the activities in the standard BTAN chapter model alongside the enhanced activities of BTAN+ chapters arranged by how they integrate into the existing three BTAN chapter program model domains of education, leadership development and mobilization, as well as how each activity supports the strategy pathway of facilitation or amplification. This model provides the minimum and standardized activity requirements that BTAN+ chapters will be expected to conduct each year of the implementation period; however, chapters may choose to engage in additional activities beyond these. As all communities are different, it is not expected that all activities will be implemented in exactly the same manner, and flexibility is provided to each BTAN+ chapter to address issues and conduct their work in ways that are most resonant to their communities. All activities will be documented as part of process measures (Section 5.5) to assess levels of uniformity and adherence to the enhanced and/or standard operating model.

Table 4: Comparison of Standard BTAN and BTAN+ Activities

Domain	Comparison of Standard and Enhanced Activities		
	BTAN Standard Model	**BTAN + Enhanced Model***	
Education	Initial Intensive BTAN Establishment Training: ▪ HIV prevention and treatment science literacy ▪ Policy advocacy and civic-engagement strategies.	**Facilitation** ▪ Participate in CRISP (intersectional stigma reduction) foundation training (see Section 7.3.1) (Year 0). ▪ Participate in structural competency training within first year of implementation. ▪ Participate in at least one annual refresher training on HIV prevention, scientific literacy policy, advocacy, civil engagement, and structural competency.	**Amplification** ▪ Localize and incorporate HPTN 096 messages through coalition outreach, other community outreach and communication, and educational channels, including raising awareness of other HPTN 096 study components (Years 0-3).
Leadership Development	▪ Monthly technical assistance call ▪ Monthly leaders' call ▪ Annual National Leaders Summit ▪ Quarterly leadership development sessions ▪ Opt-in professional learning communities	**Facilitation** ▪ Monthly BTAN+ chapter leaders/technical assistance call (Years 0-3). ▪ Initial rapid mapping exercise to identify local resources and services that may help alleviate structural impediments to HIV testing, PrEP and/or treatment for Black MSM (by end of Year 1). ▪ Annual "booster" mapping activity to assess changes in landscape of local resources and services (Years 1-3).	**Amplification** ▪ Collaborate on HCFs action planning to support CRISP intervention (Years 1-3, see Section 7.3). ▪ Annual Knowledge Exchange Symposium for BTAN+ chapters to share best practices re: HCF collaborations, resource mapping exercise, and any other amplification strategies (Years 1-3).
Mobilization	▪ 12 Chapter meetings per year ▪ 1 Advocacy event per year ▪ 1 Science event per year	**Facilitation** Convene multi-sector (e.g., education, housing, legal services, drug treatment and addiction, human services) service provider equity forum(s) in Year 1 (with follow-up events at most annually thereafter) to: ▪ Raise awareness of EHE goals ▪ Raise awareness of HPTN 096 ▪ Illustrate the connection between their services and EHE goals ▪ Encourage cooperation to leverage their services to reducing structural barriers to HIV prevention for Black MSM ▪ Create and maintain curated roster of service organizations for Black MSM	**Amplification** ▪ One annual advocacy event focused on intersectional stigma reduction with Black MSM ▪ One annual science event focused on current advances in HIV prevention and treatment (e.g., PrEP options, ART options, HIV/STI self-testing options).

*Note: Activities in the BTAN+ Enhanced Model are in addition to those in the Standard model.

5.3.5 Timeline of Activities

Pre-Implementation

- BAI resourced for scale-up and activities of BTAN+ chapters
- Formative work and partnerships with other organizations on the ground, as well as existing BTAN chapters
- Identification of communities without existing BTAN chapters and prioritization of BTAN+ chapter establishment

Ramp-Up

- Establishment of BTAN+ chapters in each intervention community
- BTAN+ chapters participate in CRISP foundation training

Full Implementation

- BTAN chapters fully operational and begin activities (may begin prior to full implementation period)
- Data/process measure metrics provided to study team

5.4 Human Subjects Considerations

The health equity strategy involves collection of descriptive organizational information over time about BTAN chapters and other service organizations in each community and does not include collection of data or private identifiable information about any individuals. As such, this activity does not meet the definition of human subjects research and 45 CFR 46 does not apply.

5.4.1 Informed Consent

As 45 CFR 46 does not apply to the health equity strategy activities, informed consent is not applicable to this activity. However, in the interest of transparency and trust-building within the community, members of BTAN and BTAN+ chapters that are located in SOC and intervention communities will be actively engaged in and informed of these activities, and will be informed that descriptive information on their BTAN/BTAN+ chapter will be collected for the purposes of this research study (see Section 5.5 for process data to be collected). They will also be informed that no data or identifiable information about individual members will be obtained by the HPTN 096 study team, analyzed, or included in any publication. SOC and intervention community BTAN and BTAN+ chapter members will also be informed that BAI will receive financial support from the HPTN to support chapter participation in these activities (see Section 5.4.3). Existing BTAN chapters in potential study communities will receive this information through engagement webinars organized by BAI prior to study implementation; this information will also be included as part of new BTAN+ chapter initiation training. Any new members to existing or

new BTAN chapters in study communities will receive this information as part of their onboarding process.

5.4.2 Confidentiality

Descriptive organizational information collected about BTAN/BTAN+ chapter membership, activity and performance will be kept confidential. No personal information about individual BTAN/BTAN+ chapter members will be collected or shared with the HPTN 096 study team, analyzed, or included in any HPTN 096 publications.

5.4.3 Compensation

Core members of each BTAN (SOC) and BTAN+ (intervention) chapter leadership will receive stipends for their roles in leading the chapter. Funding will be administered through BAI to each chapter. BAI will also receive funding for administration of BTAN and BTAN+ chapters involved in the study in SOC and intervention communities. This funding will be used to support activities related to establishment of new BTAN+ chapters in intervention communities, enhanced activities of BTAN+ chapters, increased administrative burden due to increased number of BTAN chapters, and process data collection activities in SOC BTAN and intervention BTAN+ chapters in support of the study.

5.5 Process Measures Related to the Health Equity Component

Process measure data at the BTAN/BTAN+ chapter level will be collected on an annual basis or more frequently to evaluate fidelity to and penetration of the planned health equity component. These measures are intermediary between the implementation of the component activities and achievement of the primary and secondary outcomes, and also reflect key implementation outcomes of the logic model framework (see Section 1.2.1), and thus will be important in understanding the role that this particular strategy may (or may not) have in producing the primary and secondary outcomes. Process measure data will be reviewed by the study team and Study Monitoring Committee (SMC – see Section 12.7) during the study period to make real-time adjustments to deployment of the component to improve its effectiveness. Process measures for health equity may include:

- Measures of penetration of the component activities:
    - Number of BTAN+ established in each intervention community and length of time required for establishment
    - Number of BTAN+ and BTAN coalitions achieving chapter status and time to achievement of chapter status
    - Number of meetings and attendance at each meeting for each intervention/SOC BTAN+/BTAN chapter
    - Composition of each intervention/SOC BTAN+/BTAN chapter (number of people, number and types of organizations represented, roles/positions of members)

- Number and frequency of meetings between BTAN+ chapters and local HCFs participating in the CRISP intervention, and number of different HCF engaged with BTAN+ chapter
- Metrics of engagement of BTAN/BTAN+ chapter members (e.g., number and percentage of members who participate in each type of chapter activity)
- Analytics of use of the curated resources list developed by BTAN+ chapters (e.g., website hits, repeat visitors, etc.)

- Measures of fidelity to the planned implementation of the component:
  - Number, type and timing of enhanced BTAN+ model activities completed by each intervention BTAN+ chapter
  - Number, type and timing of standard BTAN activities completed by each BTAN chapter or affiliate located in a SOC community
  - Number of sectors and agencies represented in the BTAN+ chapter equity forum (including % that agree to be on resource list)
  - Successful creation of curated resource lists within the first year of implementation (number of BTAN+ chapters who create lists and number of organizations listed)
- Indicators of contamination between BTAN+ chapters and SOC BTAN chapters (e.g. source of inspiration for activities)

6.0 SOCIAL MEDIA INFLUENCER COMPONENT

6.1 Hypothesis

Tailored messaging on the topics of HIV/STI testing, PrEP and viral suppression prioritizing Black MSM and delivered by SMIs will facilitate a reduction in intersectional stigma and an increase in feelings of social support around these topics, ultimately contributing to a reduction in HIV incidence by increasing HIV/STI testing uptake, PrEP uptake, and ART adherence among Black MSM in the intervention communities compared to the control communities.

6.2 Component Description

The SMI component will be focused around of three primary elements: HIV/STI testing promotion, PrEP awareness and promotion, and viral suppression promotion. Secondary elements will involve direct SMI support and promotion of other components of the integrated strategy. For the purposes of this study, we define a SMI as a user on social media who has established credibility in a specific industry, brand, or content area. The SMIs have access to a large audience and can persuade others by virtue of their authenticity and reach. For this study, local SMIs, defined as those whose reach is limited to a population defined mainly by their geographical area or specific sub-populations within that area, will be engaged as implementers.

6.2.1 Primary Elements

For the three primary elements, tailored, status-neutral, culturally-resonant messaging prioritizing Black MSM in intervention communities will be developed and delivered by SMIs on the topics of:

- **HIV/STI testing promotion**: The SMIs will promote messaging (self-developed or developed by others) reinforcing the importance of HIV/STI testing and providing information on how HIV/STI testing can be obtained in the community.
- **PrEP and HIV prevention awareness and promotion**: The SMIs will develop and/or push PrEP and other HIV prevention promotion content prioritizing Black MSM in their communities and provide information on where PrEP is available in the local community.
- **Viral Suppression promotion messaging:** The SMIs will push content promoting viral suppression and ART adherence prioritizing Black MSM in their communities.

6.2.2 Secondary Elements

In addition to the above primary elements which are directly related to study outcomes, the SMIs will also be asked to support and promote other components of the HPTN 096 integrated strategy, which will serve to synergistically amplify the effect of those components within the intervention communities and facilitate the transition to action. As examples:

- **Health equity**: The SMIs may promote events put on by local BTAN+ chapters (see Section 5.0), as well as community resource lists developed by BTAN+ chapters with the organizations or services included therein. BTAN+ chapters may advise SMI on content. The SMIs will be offered participation in their local BTAN+ chapter, and BTAN+ members may be identified as influencers.
- **Intersectional stigma reduction**: The SMIs may promote HCFs involved in the CRISP component (see Section 7.0), if agreed to by those HCFs, as culturally responsive locations to receive HIV/STI testing, HIV care and/or PrEP services.
- **Virtual Peer support**: The SMIs may promote the virtual, status-neutral peer support platform to Black MSM community members (see Section 8.0).

6.2.3 Implementers

SMIs will be identified according to the criteria listed in Section 6.2.4 and will be compensated to promote and/or develop content relevant to the primary and secondary elements of this component (see Sections 6.2.1 and 6.2.2 above). After undertaking a comprehensive SMI selection process (see Section 6.2.4), where adequate local influencer capacity does not exist, it will be developed (described further in the Study-specific Procedures (SSP) Manual). Section 6.3 describes SMI activities.

It is expected that 2-4 SMIs will be engaged at any given time in each intervention community for implementation of this study intervention. The exact number of SMIs in each community may change and will be determined per the process described in Section 6.2.4. Additionally,

individual SMI may change over time. While SMIs will be selected based on their access to Black MSM in the intervention community locality, in reality, there are no real geographic parameters around the reach of social media platforms and/or the SMIs. Instead, local influencers will be identified and defined as such by who their followers are, through the use of analytics of social media activity, and messages/content related to the study objectives will be geographically tailored when possible. While platforms may span borders, influencers themselves may have more of a local rather than national/global following, often referred to as micro-influencers, and will tailor content to local audiences. Social media analytics on geographic location of followers can be compared to existing data on the population of Black MSM in each community to describe potential reach of the SMIs within this population. There are a number of techniques that SMIs may also use, such as location tagging and engagement in local events, to help target study-related information to more local audiences. Additional information on mitigation of contamination risks is described in Section 6.2.5.

All SMIs will be trained by the study team on the science and objectives of the HPTN 096 study (see Section 6.3.1) but will develop their own content. In this way, content pushed by SMI will remain authentic to their social media persona, and the trust that each SMI has built with their followers will be maintained (see Section 6.3.2).

6.2.4 SMI Selection

An SMI selection process will be used to identify and formally select SMIs to participate as implementers of this component of the integrated strategy. A community advisory approach will be the foundation of SMI selection. Members of the HPTN 096 CSG and/or CAG will be enlisted to identify an initial list of SMIs that are felt to have influence within the Black MSM population generally within the geographic locale of the randomizable units, or with subpopulations of Black MSM based on age and other cultural subsets in those communities. CSG/CAG members making these recommendations will likewise be representative of broad and varied subsets of the Black MSM population in the southern US and intervention communities. After or in parallel with initial identification, a social media firm, preferably with experience in the Black southern US context, will be contracted to assess the identified SMI. This firm will be solicited following FHI 360 standard procurement procedures. The firm will conduct a brand congruence analysis on each SMI to further describe their analytics, demographics and geographic reach of followers, engagement of followers, and confirm that SMI brand/messaging do not directly conflict with the objectives of HPTN 096 (e.g., SMIs are not spreading mistruths related to HIV). Given their access to social media data and analysis tools, the SMI firm may also be asked to assess the landscape of SMIs for the purposes of identifying additional SMI candidates who could be approached to be implementers. SMIs who are deemed congruent will be invited to participate in the SMI component. Those who accept will be contracted with on an annual basis to serve as implementers of the SMI component. Compensation will be provided to each SMI commensurate with activities undertaken as implementers of this component of HPTN 096. The SMIs will be permitted to exit the contract with the HPTN 096 study and end their role as implementers.

Initial selection of SMIs will be completed within the first half of the 1-year ramp up period. Subsequently, SMI qualifications will be reviewed on a semi-annual basis with the assistance of the social media firm and CAG. If needed, additional SMIs may be engaged and brought on, and

SMIs who are no longer a good fit for the study or who remain disengaged after a process of re-engagement and quality improvement will no longer serve as a SMI for the study.

6.2.5 Limiting Contamination

Influencers will promote and share content via web-based social media platforms. Such platforms do not operate within prescribed geographic bounds. In order to reduce contamination from intervention communities into control communities, SMIs will be selected based on analytics related to their geographic reach (as described in Section 6.2.4). To the extent possible, SMIs will promote content to individuals within the intervention communities by using techniques such as the use of micro-influencers and location tagging (i.e., geotagging) to limit the reach of their messaging to the specific geographic location of the intervention community. While it is likely that SMI content and messages containing geographically-based or HPTN 096-specific information (e.g. referrals to clinics that have been through the CRISP training program or promotion of local HIV/STI testing options) may reach control communities, such messages will have limited ability to contaminate those communities, as the infrastructure and/or resources related to those components are not available to Black MSM residing in control or non-intervention communities (e.g., Black MSM residing outside of an intervention community will not have access to local HIV/STI testing options).

6.3 SMI Component Activities

6.3.1 Training

The SMIs will be trained by the HPTN 096 study team beginning in the second half of the 1-year ramp up period. They will be trained on scientific literacy, the science behind the HPTN 096 study, intersectional stigma related to Black MSM and HIV-related outcomes, technical information specific to the SMI component (i.e., PrEP, HIV/STI testing, and viral suppression), and how SMI techniques may be most impactful in a public health context. The SMIs will be trained in how to handle difficult questions related to the topic areas, and how to report social harms or other destructive conversation (e.g., dealing with "trolls" or others who intentionally post inflammatory or provocative content for the purposes of instigating controversy or conflict) to the study team. Performance expectations will be shared with the SMI. Refresher trainings will be conducted on an annual basis as a condition of contract renewal. Opportunities may be provided for sharing lessons learned and best practices among SMIs. If new SMIs are identified and engaged after study implementation, they will initially be trained separately from existing SMIs.

6.3.2 Content Development and Iteration

6.3.2.1 Development

The SMIs will be expected to develop their own content, authentic to their brand, but which serves to promote HPTN 096 messaging, integrated strategy components, and elements as described in Sections 6.2.1 and 6.2.2. The SMIs will be trained in topic areas of interest for HPTN 096 as described above in Section 6.3.1. Additionally, the HPTN 096 study team will provide SMIs with a content guide describing parameters and technical information for study-related content (see SSP Manual), and members of the study team will be accessible to SMI to

provide technical assistance. Content developed by SMIs for the purposes of this study is expected to meet the parameters in the content guide. The SMIs may also post or promote related content developed by other influencers (either involved with or not involved with the HPTN 096 study), as well as content developed by the HPTN 096 study team for other purposes. The SMIs may create content that supports or promotes HPTN 096 components either directly (for example, promoting the virtual peer support program) or indirectly (for example, more general messaging about being healthy or knowing your HIV status).

Content developed by SMIs will be pushed/posted on social media platforms. There are no parameters around the format of content that SMI may develop; acceptable content may include (but is not limited to) text-based posts, videos, images, songs, or other online media. The SMIs may post on any social media platform that they feel will reach Black MSM. This may include Facebook, Instagram, Twitter, YouTube, TikTok, personal blogs, or any other platform or app that can reach the intended audience.

6.3.2.2 Iteration

SMI messaging will need to be iterated and periodically refreshed throughout the implementation period. This will be facilitated through content monitoring and feedback by the study team (see Section 6.3.4), as well as annual refresher trainings (see Section 6.3.1).

6.3.3 Frequency of Messaging

The SMIs will be expected to have a regular social media presence, conversation, and engagement around the three main elements over the course of the three-year implementation period. Exact frequency of messaging will vary depending on message type, engagement of followers, and activity level of the SMI. Conversation and content delivery may be fluid, and other times, prescribed. If prescribed messaging is needed, the study team will communicate this via email to the SMIs.

6.3.4 Content Monitoring

The HPTN 096 study team will not attempt to change the SMI brand or police their content (particularly content unrelated to HPTN 096). However, periodic review of content by the study team, with the assistance of the contracted social media firm, will occur to ensure thematic fidelity to the study parameters and content guide. This monitoring will also confirm that SMIs are still active influencers in the social media world and still have audiences in the local geosphere of their intervention community (i.e., confirming that a local SMI for a particular community is still actively posting social media content that is reaching that community). The SMI contract renewal will be based on confirmation that the SMI is producing content for the purposes of HPTN 096 and are still active influencers in their community. The SMIs are expected to operate with integrity and abide by the community guidelines established by each individual social media platform on which they are active. Additionally, messaging that promotes mistruths related to HIV or that is in direct conflict with study themes (e.g., messaging discouraging PrEP use) will be cause for retraining the SMI and potentially for contract termination.

It is expected that SMIs will also continue developing and pushing content that is authentic to their original brand and unrelated to HPTN 096. In order to maintain brand authenticity and particularly when promoting general public health messages, SMIs will not be required to state a direct or advertised affiliation with the HPTN or this study but may do so if they wish. This is in line with standard practice of how SMIs operate. The SMIs may state an affiliation to HPTN when promoting specific HPTN 096 components or events.

6.3.5 Timeline of Activities

Pre-Implementation

- Identification and procurement of social media firm
- Enumeration of SMIs by CAG
- Brand congruence analysis of SMIs by social media firm

Ramp-Up

- Final selection of the SMIs, including contracting with each SMI
- Training of SMIs
- Development of content by SMIs

Full Implementation

- Development and promotion of content by SMIs
- Content monitoring, refresher trainings, and iteration
- Collection of process data

6.4 Human Subjects Consideration

As SMIs are considered implementers of this study component and are not research subjects or participants, and as no private identifiable information will be collected from any individuals whom the SMIs intervene upon with their social media messaging, the SMI activities are not considered human subjects research and 45 CFR 46 does not apply. As this field is expected to evolve over the course of study implementation, emerging standards related to the use of social media in the research setting will be consulted in order to minimize potential harms such as confidentiality violations and stigma.

6.4.1 Informed Consent

As 45 CFR 46 does not apply to the SMI component, informed consent is not applicable to this activity.

6.4.2 Confidentiality

Permission will be obtained from the SMIs as part of their contracting process to monitor their implementation of these study activities in order to assess fidelity to and penetration of the study activities. This monitoring will involve content analysis of each SMI's public social media content, as well as collection and assessment of metrics of engagement (see process measure data to be collected in Section 6.5). Social media content that is within the public realm only will be monitored for study purposes (i.e., private messages to and from other social media users will not be accessed by the study team or its contractors). Metrics of social media activity will only be evaluated for the purposes of process measures assessment and monitoring of SMI activity and will not be used or sold for targeting of advertising or other information towards SMIs or their followers. Individual usage of social media will not be assessed. Social media content will be collected using the publicly available posts on platforms such as Twitter, Instagram, Facebook, Tumblr, Reddit, TikTok, YouTube, and any other relevant platforms. Relevant public posts will be downloaded periodically over the study period. This data may include image and video links, posts, tweets, retweets, comments and social media demographics (i.e., number of likes, favorites). Social media platforms identify users by assigning unique ID numbers (i.e., Twitter ID), not usernames.

While identifiable fields will not be intentionally downloaded from social media (e.g., birthdate, address, email, phone number), identifiable data may be inadvertently captured as individuals post information in status updates (e.g., RT @funnyjen). Usernames will not be included as part of any analysis or coding procedures, and computer algorithms or human coders will not be used to cull, collect, and analyze identifiable information.

6.4.3 Compensation

As described in Section 6.2.3, the SMIs will be compensated for their activities directly related to implementation of this component. Compensation will not be provided to any individual social media users interacting with SMIs as part of this study.

6.5 Process Measures Related to the SMI Component

Process measure data will be collected on an annual basis or more frequently to evaluate fidelity to and penetration of the planned SMI activities. These measures are intermediary between the implementation of the SMI component and achievement of the primary and secondary outcomes and also reflect key implementation outcomes of the logic model framework (see Section 1.2.1), and thus will be important in understanding the role that this particular component of the integrated strategy may (or may not) have in producing the primary and secondary outcomes. Process measure data will be reviewed by the study team and SMC during the study period to make real-time adjustments to deployment of the component to improve its effectiveness. Process measures for SMI may include:

- Measures of penetration of the SMI activities:
    - Number of SMIs in each region/community
    - Metrics of social media engagement, including the following:

        - Clicks on links/videos
        - Time spent on links/videos
        - Number/types/demographics of followers of SMIs
        - Number and types of reposts/retweets
        - Comments (stratified by social media platform and SMI components)
        - Types of content developed

- Measures of fidelity to the planned SMI activities:
    - Retention rate of SMIs in each community
    - Frequency of SMIs postings and activity
    - Content analysis of SMIs' postings and activity as compared to content guide

7.0 INTERSECTIONAL STIGMA REDUCTION COMPONENT

7.1 Hypothesis

An HCF-level intersectional stigma reduction component to improve cultural responsiveness in the provision of health care services for Black MSM will contribute to a reduction in HIV incidence. This will be done by creating an affirming and autonomy-supportive healthcare environment that supports Black MSM engagement in HIV-related care and services and that promotes increased HIV/STI testing, PrEP uptake, and viral suppression rates.

7.2 Component Description

The CRISP component of the integrated strategy will take place at selected HCFs (see Section 7.2.3). The CRISP component is designed to optimize the healthcare environment for Black MSM by addressing the intersectionality experience of anti-Black racism, sexual stigmas, and HIV-related stigma. This will be accomplished through three phases (foundation, installation and implementation) that are aligned with the EPIS (exploration, preparation, implementation and sustainment) model (195) over the course of a one-year ramp-up period and three-year implementation period:

- **Foundation Phase:** A majority of *relevant* staff (e.g., the clinical staff who directly provide HIV treatment or prevention services, and the non-clinical staff who support or provide administrative leadership to them) at each HCF will participate in the CRISP Foundation training workshop on culturally responsive services for Black MSM, including content on integrative anti-racism and intersectional stigma, structural competency, skills practice, and accountability (see Section 7.3.1 for details).
- **Installation Phase:** HCFs representatives from key clinical and non-clinical roles (including but not limited to Champion teams) will engage in continued learning and skills application within their HIV prevention and/or care practice settings, achieved through Extension of Community Healthcare Outcomes (ECHO) activities, quality

improvement (QI) collaborative orientation, client-instructor experiences, development of CRISP action plans, implementation of a self-monitoring strategy, and collaborative problem-solving with community support (see Section 7.3.2 for details).

- **Implementation Phase:** HCFs will implement and report on site-specific CRISP action plans and self-monitoring strategies, including collaborative problem-solving with community support, as well as QI collaboratives that will foster practice transformation by facilitating knowledge exchange and technical assistance between the HCFs in the collaborative.

The CRISP model is shown below in Figure 5 and further described in Section 7.3. The CRISP component will generally employ a "whole facility" approach, recognizing the sources of intersectional stigma do not only come from clinical providers, but also any HCF staff that may encounter patients, such as front desk and administrative personnel.

7.2.1 Implementers

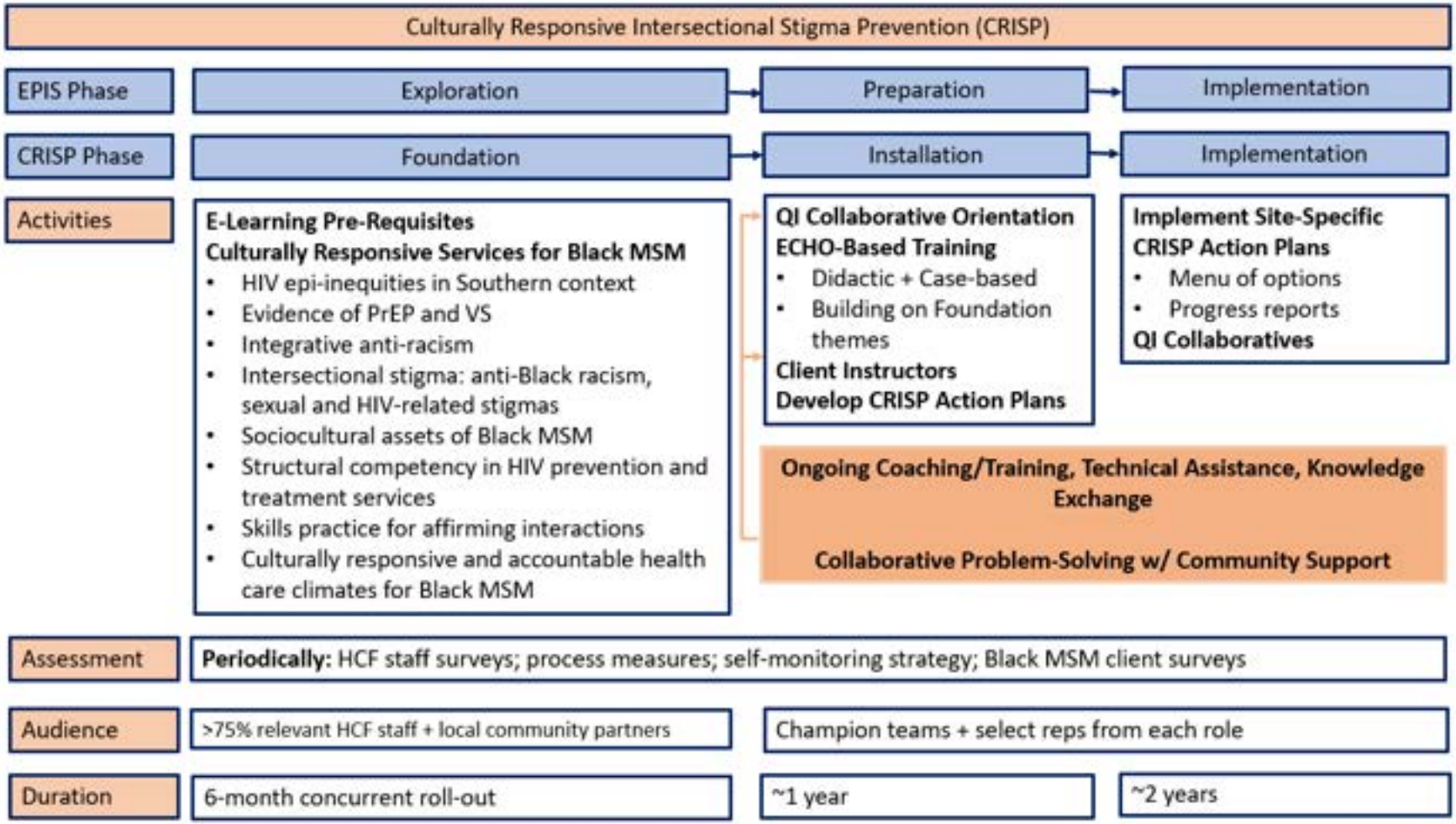
CRISP will primarily be implemented by local teams of interventionists who may include, but not be limited to individuals with expertise in intersectionality, training methodologies used with HCFs, clinical provision of HIV services, and working with HCFs to improve the quality of service provision for Black MSM. CRISP interventionists will be contracted following FHI 360 procurement procedures.

In each community, the local CRISP interventionists will be responsible for implementing the Foundation phase, as well as carrying out the ECHO curricula, facilitating QI collaboratives, and providing technical assistance. Throughout the study, CRISP interventionists will receive technical assistance and central administrative oversight by the CRISP leadership team comprised of key study team technical leads. A small team of Black MSM from each community will be trained to implement a client-instructor methodology which involves enacting a simulated client/patient role in the HCF and then rating the service quality of the experience that had with the specific HCF staff with whom they came in contact with during the simulation (see Section 7.3.2.3). The client-instructors will also be overseen by the CRISP leadership team.

Champion teams will be assembled at each HCF and will include at least one representative from key functional areas at each facility; for example, a combination of clinical staff, front-line staff, peer navigator, C-suite member, data manager and human resources representative. Champion team composition specific to each HCF will be based on organizational composition of each HCF and determined as part of the contracting process with the HCF. Champions must complete the Foundation phase of CRISP. If staff who are designated as Champions leave their position at the HCF, a new staff member will be selected to replace that person, and periodic Foundation re-trainings will be offered as needed to ensure new staff receive this training (re-trainings may be offered virtually and may combine new staff from different intervention communities for efficiency). Foundation re-trainings will be open to additional staff beyond Champion roles as resources permit. Each HCF will be compensated to subsidize Champion time for study-related activities (see Section 7.4.3).

In the Installation and Implementation phases, development and implementation of CRISP action plans and self-monitoring strategies will be led by the Champions teams at each HCF, with ongoing coaching and technical assistance provided by the local CRISP interventionist team and collaborative problem-solving done in partnership with community advisory structures, such as local BTAN+ chapters and local community advisory boards (CABs).

Figure 5: CRISP Model



7.2.2 Location

The Foundation phase of the CRISP component will involve a synchronous training that will take place, ideally in person, at central locations in each community accessible to participating HCF staff. If necessary or preferable, the Foundation training may be delivered virtually. Installation and Implementation of the CRISP component will take place at each HCF and will involve a combination of virtual synchronous and asynchronous web-based activities as well as virtual or on-site technical assistance.

7.2.3 Health Care Facility (HCF) Selection

HCF selection will involve two processes that may be iterative: 1) identification of facilities that are most likely to serve (and those with the capacity to serve) Black MSM, those that demonstrate the most need for improvement in services to Black MSM, and those that comprise a sufficient set of facilities to make an impact at the Black MSM community level; and 2) robust recruitment of the target facilities in order to gain their buy-in and willingness to participate.

7.2.3.1 HCF Identification

HCFs may include any type of facility that provides HIV-related care and/or PrEP services, including but not limited to primary care clinics, health system and/or hospital outpatient clinics, health department sexual health clinics, federally-qualified health centers, Ryan White-funded clinics, general medicine clinics, private health care offices, infectious disease clinics, pharmacies providing walk-in clinic services, and community-based organizations within the PrEP continuum. HCFs must be located within a county randomized to the HPTN 096 intervention arm.

An iterative and formative HCF identification process will use a combination of information from quantitative databases and qualitative data sources. Information from databases will be used to enumerate and characterize facilities that are current providers of HIV care and/or PrEP. Additional sources may be used to supplement information about current providers or to identify potential new providers (e.g., of PrEP).

Database sources include:

- Facility-based viral suppression surveillance data for Black MSM (CDC)
- Ryan White-funded clinics (HRSA)
- Health Center Program Awardee Data (HRSA)
- HIV care and PrEP service locations (AIDSVu)

Supplemental qualitative information will be elicited from the sources below:

- HCF preferences and perceptions survey data (formative web-based survey implemented with Black MSM in potential HPTN 096 communities)
- HPTN 096 CAG and CSG input

- EHE planning council and local health department recommendations

7.2.3.2 HCF Recruitment

A comprehensive HCF recruitment strategy will be developed with input from community members, partners (i.e., CDC, HRSA, local health departments and EHE councils), and individuals with expertise in health care leadership and quality improvement, practice transformation, and provision of HIV services in the southern US. The strategy will include proactive measures to address feasibility, such as soliciting HCF feedback on incentives (e.g. financial compensation, continuing education credits, facility certification, access to technical assistance, etc.) that may facilitate their participation, and how the training approach could be tailored to meet their preferences. The strategy will also emphasize how participation in this component can help communities achieve EHE goals.

The recruitment strategy will be implemented with the target HCFs after community randomization has been completed and target HCFs have been identified in each intervention community. Members of the study team will implement the strategy by undertaking HCF education and engagement activities, in order to gain HCF buy-in and commitment to participate.

HCF agreement to participate in this study will confer a commitment to participation in all trainings as specified in the protocol, a commitment to identification of a Champion team within the HCF, a commitment to development of a CRISP action plan, a willingness to engage with local community organizations and partners for collaborative problem-solving, and provision of process measure data to the study team. HCF participation will be confirmed upon signing an agreement to participate in the study. The agreement will include compensation to HCF for their participation in this study component as described in Section 7.4.3.

7.2.3.3 Number of HCF

Due to the variability across potential communities, the qualitative nature of some of the data to be assessed, and the need for HCFs to agree to participate, it is difficult to estimate the number of HCFs that would participate in any given community. It is anticipated that between 10 and 20 facilities will participate in each community, on average.

7.3 Intersectional Stigma Reduction Activities

7.3.1 Foundation Phase

In the Foundation phase, staff from each participating HCF in an intervention community will participate in a regional (i.e., inclusive of all participating HCFs in a given community) synchronous training on Culturally Responsive Services for Black MSM. The training will require a minimum of 12 training hours, but delivery may be tailored to the preferences of each intervention community (for example, segmented into shorter sessions provided over a number of days or period of weeks, or condensed into longer sessions provided intensively over 1.5-2 days). Multiple training dates will be offered in each community in order allow HCF staff to cycle through the training rather than all being away from regular duties at one time, and to provide enough opportunities to ensure the target number of HCF staff and providers are

reached. Ideally, the training will be provided in an in-person setting; if necessary due to COVID-19 or other factors, it may be provided virtually. While the curriculum content will be standard across all intervention communities, the CRISP interventionist teams will work with the HCF in their community to determine the most appropriate schedule for training delivery. A target of >75% of relevant (i.e., related to provision of HIV services) staff at each participating HCF will be trained.

The standard curriculum to be used for this Foundation training will be derived from existing evidence-based training curricula on cultural responsiveness, HIV stigma reduction, anti-racist practices in health care, anti-Black racism, contributions and resilience of Black gay Southerners and similar topics, but will be refined by the CRISP training team to meet the specific needs of this study. Topics covered in the training will include (but are not limited to) the following:

- Presentation of HIV epidemiological inequities, including intersectional patterns of race, transmission category and geography
- Review of evidence related to PrEP, general HIV prevention, viral suppression, and HIV testing
- Discussion on integrative anti-racism
- Understanding intersectional stigma: anti-Black racism, sexual stigmas, and HIV-related stigma
- Identification of sociocultural assets of Black MSM
- Building structural competency in HIV prevention and treatment services
- Skills practice for affirming interactions
- Trauma-informed care
- Creating culturally responsive health care climates for Black MSM
- Creating an accountable practice community

Implementation of the Foundation phase will occur in parallel across all intervention communities during the second half of the ramp-up period. Interventionist teams will undergo training during the first half of the ramp-up period.

7.3.2 Installation Phase

CRISP Installation will begin for any given intervention community after that community completes the CRISP Foundation phase. Completion of the CRISP Foundation will occur when all offered trainings have been conducted in that community and the target number of staff at all participating HCF have been trained. Installation will include the following elements: 1) QI collaborative orientation, 2) ECHO, 3) knowledge exchange, 4) e-learning modules, 5) client-instructor experience, 6) technical assistance, 7) self-monitoring, 8) collaborative problem-solving, and 9) development of CRISP action plans. The Installation component will be supported through a web-based portal that will provide HCF staff with a central location to access all elements and track their utilization, and to connect with their QI collaborative and

other participating HCFs, and will provide the CRISP interventionist teams with a tool to organize trainings and other CRISP activities and materials.

7.3.2.1 QI Collaborative Orientation

Early in the Installation phase, HCFs will participate in an asynchronous, web-based orientation to QI collaboratives, including expectations for working within a QI collaborative for this study, as well as measurement and self-monitoring expectations and strategies. QI collaboratives will begin to be organized during Installation with participating HCFs, as is further described in the SSP.

7.3.2.2 ECHO

The CRISP interventionist teams will build on themes highlighted in the Foundation phase by using an ECHO-based model for case-based learning and knowledge exchange (196, 197) to facilitate translation of the Foundational phase concepts into best practices for providing HIV prevention and care services to Black MSM within HCF settings. The ECHO-based model will employ a train-the-trainer approach and will be delivered over a series of synchronous web-based sessions to a subset of HCF staff who represent the key roles in the facility, grouped into clinical and non-clinical cohorts. ECHO content will build on content covered in the Foundation training by extending it to clinical application, and will include a brief didactic component highlighting specific topics (e.g., impact of implicit bias on PrEP decision making; intersectional stigma reduction strategies to improve HIV testing; understanding linkage between intersectional stigma, allostatic load, and HIV viral suppression; etc.) followed by a related case presentation and discussion. Standard didactic curricula (clinical and non-clinical) for ECHO sessions will be developed centrally and will be delivered over the first year of the study intervention period; cases will primarily be more regionally focused and will be submitted by the participating HCFs in each community, and will focus on actual clinical and systems-level challenges being experienced by the facilities related to the topics in the standard didactic curriculum. Each session will be 1-2 hours in length and will be offered approximately once per month. Continuing education credits will be offered for each session, and sessions will be recorded and housed on the CRISP web-based portal for future viewing.

7.3.2.3 Client-Instructor (CI) Experience

Skills learned in the Foundation and ECHO trainings will be practiced and reinforced through the Black MSM CI supportive feedback methodology (analogous to “standardized patients” in the medical literature) (160, 198, 199). CI will act as independent raters of intersectional stigma -- both its structural and procedural manifestations as well as the interpersonal manifestations -- in each HCF. CI will be Black MSM who are hired and trained in each intervention community to rate facilities and coach providers and HCF staff.

A CI experience is a simulated visit at an HCF. In these visits, the CI will walk through a typical clinic visit and use qualitative scales developed into checklists to rate the visit on measures pertaining to intersectional stigma. At the end of the visit, the CI will provide all staff members who he interacted with during the visit with supportive feedback and coaching. While CIs will

primarily interact with the clinician, they may also rate other non-clinical aspects of their visit, such as the welcoming behavior of the front desk staff and the clinic environment.

Within the first year of the study intervention period, the goal will be to conduct one CI experience with each applicable staff member at each participating HCF (i.e., each staff member a patient would come in contact with along the pathway of their HCF visit). One CI experience is expected to cover multiple staff members (because the client is expected to come into contact with multiple staff members during the experience). The purpose of the CI experiences within the first year is to provide feedback on the Black MSM's experience of intersectional stigma at their facility, and to allow HCFs to use the feedback to prepare for developing and implementing their CRISP action plans. In subsequent years, the goal will be to conduct one experience with a subset of at least 50% of relevant staff at the HCF to help facilities' monitor and evaluate progress since Year 1 and use the feedback to optimize stigma reduction measures. More experiences may be requested, as well as "booster" sessions for new staff. Providers will be encouraged to share feedback gained from CI experiences with additional staff members at their facility.

Independent ratings by CI will be reported in an anonymous manner to the study team, and data will be triangulated with HCF worker self-assessments (see Section 7.3.5) to characterize intersectional stigma at baseline and post-implementation. Ratings for the purposes of describing intersectional stigma will be done at the facility-level and will not identify any individual HCF staff, CIs, or clients.

7.3.2.4 E-Learning Modules

E-learning modules may be housed on the CRISP portal to be accessible to all participating HCF staff. E-learning modules may be used as pre-requisites for the Foundation phase or for specific ECHO sessions and may also include technical content that is more specialized or potentially not applicable to all HCF. E-learning modules may also provide an opportunity for additional clinical training resources, such as modules on clinical PrEP provision. Some modules may provide continuing education credits. E-learning modules may be developed by the study team or may link to existing training resources developed by external groups or experts. There is no prescribed dose for provision of e-learning modules; rather, the aim is to provide supplemental and supportive training and link to existing resources.

7.3.2.5 Knowledge Exchange

The CRISP web-based portal will facilitate exchange of information between participating HCF staff through a Knowledge Exchange utility. The Knowledge Exchange may include message boards and forums, as well as a repository for posting of pertinent resources and information that could be useful to those involved in CRISP. The intent of the Knowledge Exchange is to provide a forum for sharing of lessons learned and experiences, as well as house existing resources.

7.3.2.6 Technical Assistance

Participating HCF may make technical assistance (TA) requests to the central and/or regional training hub teams at any point during the study intervention period. TA will be requested via the

CRISP web-based portal. Responses may also be provided via the portal, depending on the nature of the assistance requested. The portal will also enable tracking of TA requests and responses and response rate, to facilitate process data reporting.

7.3.2.7 HIV Cascade Self-Monitoring

Participating HCF will be expected to undertake self-monitoring strategies throughout the course of the study and beyond. Given what is likely a large differential in baseline monitoring capabilities and resources, strategies used by HCFs will vary. Self-monitoring will be emphasized as a critical element of addressing intersectional stigma and assessing impact on outcomes (e.g., PrEP use, viral suppression) for Black MSM. Specifically, HCF will be expected to monitor their own facility data on metrics related to the HIV cascade, such as HIV testing, PrEP provision, linkage to care, retention in care, and viral suppression, by race and sexual orientation. Facility data will not be reported to the study team, but progress on implementing self-monitoring measures will be reported in the brief progress reports (see Section 7.3.3). Self-monitoring measurements may also be used as feedback to HCFs within the QI collaborative process. The purpose of self-monitoring is to help facilities assess if their efforts are making progress and having an impact, to provide a mechanism of accountability at the facility level, and to encourage facilities to critically examine HIV outcome disparities among their patient populations.

Training on self-monitoring strategies will be provided during the Foundation phase, during the QI collaborative orientation, via ECHO sessions, and e-learning modules. TA will also be available to support self-monitoring efforts.

7.3.2.8 Collaborative Problem-Solving

HCF will be encouraged to engage in collaborative problem-solving with community partners, including BTAN+ chapters participating in this study. Collaborative problem-solving will provide HCF with an opportunity to build lasting community infrastructure to contribute to long-term EHE goals. Community engagement will also be a component of the ECHO curriculum.

7.3.2.9 CRISP Action Plans

HCFs will develop CRISP action plans within the first year of the study intervention period. The development of these plans will be led by the identified Champion teams at each HCF (see Section 7.2.1). CRISP action plans are expected to reflect skills and knowledge acquired through the CRISP Foundation and ECHO trainings and include actionable changes and goals to address intersectional stigma reduction within the context of HIV care and service provision for Black MSM. HCF may choose from a menu of options for their action plans. HCFs may choose more than one option for their action plans. Action plans will emphasize problem-solving and application of skills within the context of HIV care and service provision.

HCF should determine which strategies may be most meaningful in their local context in consultation with their community-based advisory structures (e.g., BTAN+ chapters, CABs, etc.). Community advisory structures may assist in developing materials, resources, and/or activities in support of CRISP action plan goals.

7.3.3 Implementation Phase

7.3.3.1 Action Plan Implementation

Implementation of CRISP action plans will occur within the Implementation phase of CRISP, over approximately the last 2 years of the study intervention period. A HCF will be considered to have entered the Implementation phase once it concludes the ECHO curriculum and submits its CRISP action plan to the study team. Action plan implementation will be facilitated through production of semi-annual brief progress reports completed by Champion teams on behalf of their HCFs and submitted to the CRISP leadership team for documentation purposes and local interventionist team to facilitate provision of technical assistance. The purpose of the progress report is for HCFs to hold themselves accountable and to enable the HPTN 096 study team to understand and describe actionable changes being made at HCFs. Progress reports can also form a basis for identifying the support HCFs may need from the local CRISP interventionist team or community partners if change is not happening at the speed intended. HCF may adjust or revise the goals in their action plans over the course of the study period. HCFs will be provided with a template for reporting their progress to the study team.

7.3.3.2 Quality Improvement (QI) Collaboratives

QI collaborative work will continue during the Implementation phase. The purpose of the QI collaboratives is to further support practice transformation, the accomplishment of intersectional stigma reduction goals, and improvement in clinical outcomes (e.g., PrEP use, viral suppression) through sustaining connections with other participating HCFs workings towards similar goals. This approach will facilitate learning and sharing of best practices across these HCFs, and will allow for additional targeted training, technical assistance, or other skills-building activities in support of related goals over the Implementation period. QI Collaboratives will be facilitated by the local CRISP interventionist teams with oversight provided by the CRISP leadership team. Refer to the SSP for additional details on implementation and organization of QI collaboratives.

7.3.3.3 Continuation of Installation Activities

Self-monitoring is expected to be on-going during the Implementation phase, as well as collaborative problem-solving, and HCF may continue to access resources such as e-learning modules and ECHO recordings. CI experiences will continue during this phase as well, as described in Section 7.3.2.2 above. Foundation re-training may occur on an as-needed basis.

7.3.4 Timeline of Activities

Pre-Implementation

- Selection and recruitment of participating HCFs
- Curriculum refinement and development
- Selection/hiring of CRISP interventionist teams

Ramp-Up

- Training of CRISP interventionist teams and preparation for implementation (first half of ramp-up)
- Foundation phase completed at all HCFs (second half of ramp-up)

Full Implementation

- Installation phase begins
- Completion of ECHO curriculum and CRISP action plans by end of Year 1
- Implementation phase in Years 2 and 3

7.3.5 Assessments

Measures of intersectional stigma will be assessed pre- and post-implementation of the CRISP component with HCF workers who participate in the activities, as well as Black MSM clients of participating HCF. Anonymous surveys will be implemented to collect this information.

7.3.5.1 HCF Workers

In health care workers, surveys will be conducted annually to assess measures related to intersectional stigma and implicit bias, beginning prior to participation in the Foundation training and ending at the end of the 3-year intervention period, but will only be linked together in time with a unique participant identifier. Surveys will be administered electronically, and the electronic survey implementation tool will have the capability to ensure survey responses remain anonymous and the unique identifier cannot be linked to the worker's identifiable information, but will also have the ability to track which workers have completed the survey for the purposes of continuing education credits and related to the certification pathway. Results of the surveys will be aggregated and described at the facility level.

7.3.5.2 Black MSM Clients

Anonymous client surveys will also be administered periodically with random samples of Black MSM clients at each HCF. The purpose of the surveys is to assess a measure of experienced intersectional stigma at HCF, as well as quality of care and responsiveness to needs of Black MSM. Clients will not be longitudinally followed or enrolled in the study (separate random samples will be used at each timepoint). Results will be aggregated to the facility level and triangulated with the health care worker surveys and independent rater (CI experience) assessments to help characterize intersectional stigma at the facility, assist with quality improvement efforts, and describe any changes over time.

7.4 Human Subjects Considerations

The CRISP component of the integrated strategy will not involve enrollment of individuals, but will include collection of four types of data, each of which have different human subjects' considerations:

1. Health care worker survey data: Anonymous, annual surveys will be administered to health care workers as described in Section 7.3.5. While HCF workers will not be enrolled in the study, the collection of this survey data with individual health care workers is considered human subjects research. However, given that the data will be anonymized, it is expected that this activity will meet the definition for exempt under 45 CFR 46.104(d)(2)(i).

2. Client surveys: Anonymous client surveys will be administered with separate samples of Black MSM clients; this activity is considered human subjects research. As these clients will not be enrolled in the study and data will be collected anonymously, it is expected that this activity will meet the definition for exempt under 45 CFR 46.104(d)(2)(i).

3. Process measure data on HCF: descriptive organizational information will be collected over time about each HCF and their participation in the CRISP activities; this does not include collection of data or private identifiable information about individuals. As such, this activity does not meet the definition of human subjects research and 45 CFR 46 does not apply.

4. CI: Client-instructors acting as independent raters will provide ratings of HCF workers in the areas of structural, procedural and interpersonal intersectional stigma. While qualitative feedback will be provided to the HCF worker as part of the CRISP activities, specific ratings to be used as study data will not be provided to the worker and will be anonymized and aggregated at the facility level and triangulated to characterize intersectional stigma at each facility. As an assessment will be made of individuals, this is considered human subjects research; however, because the assessment will be anonymized and aggregated, it is expected that this activity will meet the definition for exempt under 45 CFR 46.104(d)(2)(i).

7.4.1 Informed Consent

As each data collection aspect for this component is expected to be exempt or does not meet the definition of human subjects' research, written informed consent will not be collected for any of the four data collection activities described above in Section 7.4. However, in the interest of transparency, all health care workers participating in CRISP activities will be informed of the nature of their HCF participation as part of a research study and will be asked to agree to complete the anonymous health care worker survey in order to receive continuing education credit for their individual participation in CRISP and in order for their participation to count towards the certification pathway of their facility. They will also be informed of the types of data to be collected about their HCF (see Section 7.5). Health care workers will also be informed that they may be rated by independent raters (but this rating will not be tied to their name or identity)

and that they may be provided with qualitative feedback from these raters (in their client-instructor role) in order to improve cultural responsiveness skills with Black MSM.

Clients completing the anonymous survey will also receive brief information summarizing the purpose of the survey, how the information will be used, and confirming that the survey is completely anonymous (i.e., responses will not be tied to their identity or private information).

7.4.2 Confidentiality

All survey data with health care workers and clients will be completely anonymous and will not be tied to an individual's identity or private information. Responses provided in surveys by health care workers and ratings of workers provided by independent raters will not be linked to health care worker identity and will not be provided to supervisors or used to evaluate employee job performance or compensation. CI experiences will be kept confidential between the client-instructor and the health care worker and will not be reported to the study team. Client survey responses will also be anonymous and will not be linked to the client or provided to their health care provider. Quality of care provided to the client will not be impacted by their completion of a survey or the responses they provide.

7.4.3 Compensation

HCF will be funded to designate and support dedicated Champion teams during the entire implementation period, and to cover other staff time in undertaking CRISP activities (including Foundation training activities and provision of process measure data).

7.5 Process Measures related to the Intersectional Stigma Reduction Component

Process measure data at the HCF level will be collected on an annual basis or more frequently to evaluate fidelity to and penetration of the planned implementation of the CRISP component. These measures are intermediary between the implementation of the CRISP component and achievement of the primary and secondary outcomes, and also reflect key implementation outcomes of the logic model framework (see Section 1.2.1), and thus will be important in understanding the role that this particular strategy may (or may not) have in producing the primary and secondary outcomes. Process measure data will be reviewed by the study team and Study Monitoring Committee (SMC) during the study period to make real-time adjustments to deployment of the component to improve its effectiveness. Process measures for CRISP may include:

- Measures of penetration of the component activities:
    - Number, types and proportion of staff who complete CRISP Foundation and Installation components
    - Number and types of participating HCF in each intervention community
    - Numbers and roles of Champions identified at each intervention HCF
    - Retention rate of Champions at each intervention HCF (annual)
    - Number and roles of staff participating in ECHO sessions

- Number of TA requests per HCF

- Measures of fidelity to planned implementation of CRISP
  - Number of HCF developing CRISP plan and time to completion
  - Number and proportion of applicable providers who complete a CI experience at each intervention HCF
  - Proportion of ECHO sessions completed by HCF staff
  - Progress reports submitted (and potentially goals completed or progress towards goals made)
  - Number and description of QI collaboratives established, number of HCFs participating, and metrics HCF engagement with QI collaboratives
  - Meetings with BTANs and other community advisory structures in support of CRISP plan goals
  - Utilization metrics of Knowledge Exchange utility in CRISP portal
  - Proportion of facilities conducting self-monitoring as reported in progress reports

8.0 VIRTUAL PEER SUPPORT COMPONENT

8.1 Hypothesis

Promoting and providing virtual peer support to Black MSM for HIV prevention and treatment will contribute to a reduction in HIV incidence by increasing support for HIV and STI testing, PrEP and ART uptake and adherence, and sustained HIV prevention and treatment engagement for this population in the intervention communities compared to the SOC communities. Peers will accomplish this by modeling, supporting, and enhancing motivation for positive health behaviors, as well as facilitating linkage to HIV prevention and treatment, and other needed social services.

8.2 Component Description

Peer support workers will be trained and compensated to provide coaching and support via a virtual platform. Although the intervention will be virtual-focused, it will not prohibit face-to-face meetings. Such face-to-face meetings are expected to be rare and will only take place if requested by the client, upon agreement of the peer-worker and if additional resources (e.g., for transportation for either the peer worker or the client) are available.

Support may be provided one-on-one or within a group (e.g., group chat), and may be on-demand or pre-scheduled. Where available, the virtual platform will provide access to local HIV and STI testing options, particularly the provision of mail-in self-testing and/or sample collections kits. The peer support component will be managed centrally and will not be affiliated with any specific HIV prevention, treatment, or social service facility.

The virtual peer support component is not a traditional peer navigation or case management program. Peer navigators serve to guide peers through the healthcare system and work to overcome obstacles that are in the way of the peer receiving the care and treatment they require. They help to identify needs and link peers to appropriate resources and health care. Peer support workers will provide motivational, emotional, and informational support to peers. This support seeks to provide an augmented network of support and reinforcement of positive and healthy behavior change. The peer support workers will also be trained to share information about organizations that provide HIV care, HIV prevention, PrEP and other services, including, but not limited to, legal, social, food, housing, substance use, mental health and health care assistance programs, available in the intervention communities. As part of the health equity component, BTAN+ chapters in each intervention community will develop up-to-date and curated listings of these types of local resources, as well as hold equity forums with service organizations to facilitate sensitization to the needs of Black MSM. These databases of local resources will facilitate the peer support workers' goal to strengthen awareness of and access to these resources. Additionally, the peer support workers will be supervised by a licensed clinical mental health professional who will be knowledgeable about peer support worker needs and requirements and can support the peer workers in linking peers to navigation and case management support services as needed.

Once trained, the peer support workers will have demonstrated competencies in the following types of support:

- HIV, PrEP, nPEP, other HIV prevention options, and ART education
- Adherence to PrEP, ART and medical care
- HIV/STI testing
- New HIV diagnosis
- Addressing intersectional stigma (anti-Black racism, sexual stigmas, HIV-related stigma)
- Self-care
- Information about national and local resources and assistance programs, Black MSM-centered health services, and the cost and insurance coverage of medications (PREP/ART) and medical care
- Multicultural competency (as it relates to a range of self-identities and the heterogeneity of the HIV epidemic for Black MSM in the southern US)

Peer support workers will have shared experience and a shared community membership with those whom they are supporting, be self-reflective of them and be trained to know when to share these experiences with others in a supportive way. Participants will be matched with peer support workers within the virtual platform based on limited characteristics (e.g., age, HIV status, location) and availability, taking participant preference into account when possible. Peer support workers will receive standardized training and supervision, which will consist of ongoing monitoring and check-ins. During check-ins, continued education on HIV prevention and care topics will be provided, as well as resources and tools for self-care (e.g., managing support

fatigue or vicarious trauma), support for difficult scenarios, and the maintenance of appropriate boundaries.

The program will be promoted via various types of advertising and other components of the integrated strategy, including by the SMIs, the clinics participating in CRISP, and the enhanced program activities of the BTAN+ coalitions. In addition, local PrEP and HIV care facilities in the intervention communities will be informed of the program and serve as a resource for Black MSM who might benefit from peer support services. It is through these avenues that Black MSM will be linked to the virtual platform and peer support workers.

8.2.1 Implementers

This component of the integrated strategy will be implemented by peer support workers and those who oversee the program centrally.

8.2.2 Location

The peer support component will generally take place virtually such that all communications between the participant and peer support worker will be private and confidential (including voice and/or video calls or short service messaging [i.e., texting]) and are built-in within the platform, with no physical fixed location. However, peer training and supervision may take place virtually or in-person. Although most peer support sessions will take place virtually, face-to-face meetings are not prohibited.

In the rare event a participant requests to meet with a peer support worker in-person, they will discuss and agree upon the date, time and location that is safe, public, easily accessible and a place where they are both comfortable meeting. In advance of the meeting, the peer support worker and participant will set expectations for their face-to-face meeting, such as deciding what the purpose of the meeting is, or what they are and are not comfortable discussing. Peer support workers will be trained in best practices for protecting the identity and privacy of anyone they work with, including in the context of face-to-face meetings. Participants will also be encouraged to inform someone they trust who they are going to meet and where they are meeting as an added safety measure.

Participants who reside in the intervention communities (which will be based on self-reported provision of a zip code or county) will be eligible to join the program.

8.2.3 Inclusion/Exclusion Criteria

Peer support will be offered with an HIV-status neutral approach to self-identified Black men (inclusive of cisgender and transgender men) who self-report a history of sex with other men, are 15 years and older, and who live in an intervention community.

For those who are not eligible to participate in the virtual peer support component, publicly available information for HIV-related support (e.g., HIV/AIDS hotlines listed at https://hab.hrsa.gov/get-care/state-hivaids-hotlines) will be provided.

8.2.4 Participant Discontinuation

Peers who are found to be ineligible for the peer support intervention, or who violate any rules determined for participation in the intervention, may be removed from the virtual platform. Any rules governing participant conduct within the virtual platform will be outlined in the SSP.

8.2.5 Component Size

We estimate that approximately 50,000 Black MSM will reside in our intervention communities, and that there will be an increasing percentage of Black MSM who use the study's virtual peer support platform over the course of the three-year implementation period, ranging from 10% of the Black MSM population in each intervention community in Year 1 to 30% in Year 3. Based on this estimate, we anticipate providing peer support to approximately 5000 Black MSM in Year 1, 10,000 Black MSM in Year 2 and 15,000 Black MSM in Year 3. We project the need to hire approximately 200 peer support workers over the course of the three-year implementation period. On average, we estimate approximately 25 peer support workers for each intervention community. This projection is based on an estimate that one peer support worker could support at least 75 clients per year. The level of effort required by the peer support workers will vary based on their individual capacity and the needs of the peers assigned to them. We anticipate that there will be a wide range of interaction duration (sessions ranging from a few minutes to other potentially lasting an hour or more). We will continuously monitor the amount of effort spent by each peer support worker and we will expand our pool of peer support workers if required.

8.3 Component Activities and Timeline

The following activities are planned for the virtual peer support component:

<u>Pre-implementation:</u>

- Identify person(s) to provide peer-worker supervision and support
- Create peer-worker training curriculum
- Identify entity to create and maintain the virtual peer support platform
- Create the virtual peer support platform
- Identify local resources, prioritizing options that are Black MSM-centered, and determine how the peer workers will have access to updated information (e.g., facility services, hours, etc.). This activity will be done in collaboration with the local BTAN+ coalitions.

<u>Ramp-up Period:</u>

- Identify peer support workers
- Conduct peer support worker training
- Test and practice using the virtual peer platform, including setting up test cases in each of the intervention communities

Full Implementation:

- Promotion of virtual peer support program
- Provision of virtual peer support in all intervention communities
- Provision of peer supervision and support
- Conduct refresher peer support worker training, as needed
- Onboard new peer support workers, as needed
- Monitor and maintain the technical aspects of the virtual peer platform
- Monitor encounter measures and needs, adjust the platform and/or content if needed
- Maintain access to updated local resources for peer workers in collaboration with the local BTAN+ coalitions

8.4 Human Subjects Considerations

While clients of the virtual peer support platform will not be enrolled in the study and will not be considered research participants, data will be collected on individual clients and their use of the platform, and as such, client-level data collection activities (see Section 8.5) constitute non-exempt human subjects research.

As described in Section 8.5, peer worker-level data may also be collected to assess fidelity to and penetration of the implementation plan. As peer workers are considered implementers of this study activity and are not research subjects or participants, and data collected are only for the purposes of evaluating peer worker implementation activities, the peer worker-level data collection activities are not considered human subjects research and 45 CFR 46 does not apply.

8.4.1 Informed Consent

An electronic consent form must be completed before a participant can access the virtual peer support platform. As this component does not require participants to provide their names to participate, and the activities are low risk, it is expected that a waiver of *signed* consent will be granted under 45 CFR 46.117(c)(1)(ii). Instead, there will be a checkbox acknowledging that the person has read and understood the consent and agrees to participate in the research. A template for this consent form is included in Appendix II.

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian permission will be requested for those 15 to 17 years old. These participants will still be required to provide assent by completing the electronic consent in the same process used for adults. When any participant first accesses the peer support platform, a peer support worker will orient them to the app, including review of the elements of the informed consent form. Peer support workers will be trained to provide additional information to those younger than 18 to ensure that they understand that they are participating in a research study and how to safeguard their own privacy. All participants will have access to a copy of their informed consent form within the platform.

8.4.2 Confidentiality

No personal identifying information will be collected from those participating in the virtual peer support platform. The virtual platform will have built-in secure two-way messaging (for text) and voice calling; therefore, clients will not be required to share their phone numbers or other identifying information. The only exception to this type of exposure will be for participants who request in-person assistance. Peer workers will be trained in how to keep all personal information confidential if they are provided this information for the rare occasion of in-person support. Prior to gaining access to use the virtual platform, all clients will be informed of risks associated with use of the virtual platform and measures to take to protect information on their devices. All communications within the platform will be maintained on a secure, encrypted, and HIPAA-compliant server.

8.4.3 Compensation

Peer support workers will be compensated for their work. Clients will not receive compensation for participating in the virtual peer support component.

8.5 Process Measures related to the Virtual Peer Support Component

Process measure data will be collected on an annual basis or more frequently to evaluate fidelity to and penetration of the planned virtual peer support activities. These measures are intermediary between the implementation of the component and achievement of the primary and secondary outcomes, and also reflect key implementation outcomes of the logic model framework (see Section 1.2.1), and thus will be important in understanding the role that this particular component may (or may not) have in producing those primary and secondary outcomes. Further, process measure data may be reviewed by the study team and SMC during the study period to make real-time adjustments to deployment of the component to improve its effectiveness.

The peer worker-level process measures may include:

- Measures of penetration:
  - Number of peer support workers trained
  - Number of peer/client matches
  - Number of interactions with clients
- Measures of fidelity:
  - Duration of service for each peer support worker
  - Completion of acceptability assessment (end of peer support worker participation)
  - Measurement of the type of support provided during each session (e.g. topic areas, if the visit was virtual or in-person; data to be collected in a way to minimize peer worker burden, such as a via a pop-up box, and/or a drop-down menu)

The client-level process measures may include:

- Measures of penetration:
    - Number of clients, limited sociodemographic characteristics and frequency of use (e.g., have you used it before, y/n or a range (first time, 1-3, more than 3))
    - Measurement of where clients learned about the platform
- Measures of fidelity:
    - Satisfaction survey (e.g., simple single-item assessment for a random number of sessions)
    - Acceptability and usefulness assessment (e.g., several-item assessment for a random number of sessions)

9.0 MONITORING EHE PLANS

In order to measure background (and possibly confounding) EHE activities across all participating jurisdictions, the study team will track those EHE activities that include or target Black MSM or that directly overlap with the study interventions. The study team will extract information from the EHE plans developed in each jurisdiction at baseline and on an annual basis to determine any changes over the course of the study. Using the EHE plans, the study team will create a propensity score (see section 12.8) based on data such as (i) whether the jurisdiction is implementing strategies similar to any of our four components (ii) whether the jurisdiction is implementing other relevant strategies that may affect our primary outcomes, and (iii) their target population (e.g., whether the efforts include or provide a tailored focus on Black MSM). If needed, the study team will ask for additional data from the EHE committees and/or local health departments to complete the scoring. This monitoring plan will not assess the outcomes of these activities.

10.0 CROSS-SECTIONAL ASSESSMENTS

Two cross-sectional assessments will be conducted for this study: one at baseline (within the ramp-up period), and the other after the 3-year implementation period ends (post-implementation assessment). There is no longitudinal follow-up in HPTN 096. The purpose of the baseline assessment is to provide data to control for baseline differences, optimize the methodology, and improve the power of the post-implementation assessment. The purpose of the post-implementation assessment is to collect cross-sectional data from the Black MSM population, in keeping with the primary objectives (PrEP use and viral suppression) and many secondary and exploratory outcomes of the study. Each assessment is planned to be conducted over the course of 6 months or less. For the post-implementation assessment, an additional three-month "grace period" may be granted for communities having difficulty meeting the six-month timeframe. This section describes the sampling methodology, components, population and sample size for each assessment.

10.1 Sampling Methodology

A starfish sampling approach (the combination of venue-time-based and respondent-driven sampling) (187) will be employed to recruit and enroll individual participants in both

intervention and control communities to complete the cross-sectional assessments. To minimize the potential for contamination, recruitment activities will deliberately avoid large events that may bring in large numbers of individuals from outside the community (e.g., such as gay pride).

Starfish sampling begins with an assessment of venues (physical spaces like bars and clubs); events (Balls, Black Pride Events, and the like); and/or virtual venues (social apps, dating apps) frequented by the population of interest. In each community we will conduct assessments of venues appropriate for sampling, based on frequency and volume of use by Black MSM, as well as current public health recommendations due to COVID-19. Men will be approached in these venues (physical and/or virtual) and invited to participate in the assessment. In addition, the study team will work with local partners to advertise for the assessments and build acceptance and willingness for community member participation. Advertising may take place via virtual (apps commonly used by Black MSM, social media, via SMIs, etc.), physical (palm cards, posters, flyers, etc.) and media (TV, radio, newspaper ads) methods.

Starfish sampling then goes further, and offers men sampled at venues the opportunity to assist with finding other men in their social networks who might be interested in participating. Typically, three uniquely numbered coupons are offered to those men who agree to distribute them to other Black MSM who might be interested, and these coupons, as in typical respondent-driven sampling methodology, are redeemable for incentives. The index men sampled at venues also receive additional compensation for each person they refer who subsequently engages in the study.

Once an individual is found to be eligible, and agrees to participate in the assessment, there is no individual assignment or randomization to a group. Instead, participants will be categorized according to the random assignment of their community (intervention or control). The community randomization will have been completed prior to the baseline assessment. The methods used in the assessment will be the same across communities in order to maximize comparability. However, there will be inherent variation across the communities given that some may have few or even no fixed physical venues for Black MSM, and others may have a greater proportion of event/time-limited venues (such as House Balls). Virtual venues may also vary by community and region. When virtual venues are the recruitment source, participants will be met by study staff in a physical space that they agree on for blood collection.

10.2 Cross-Sectional Assessment Locations

Assessments for the cross-sectional component may be conducted in the field at venues used for recruitment. In these cases, assessments may be conducted in mobile vans or pre-determined locations at the venue to create a private space for participants. For participants referred to the study through respondent-driven-sampling or who are recruited from a virtual venue, assessments will be done at a pre-determined physical location, for example, space within a local clinic, community-based organization, health department, or at a future venue event. Details regarding plans for conduct of the assessments will be outlined further in the SSP manual. For all assessments, trained study staff will be collecting the samples and administering the CASI questionnaire.

10.3 Cross-Sectional Assessment Components

Each assessment will consist of two components: blood collection and the completion of questionnaires (see Appendices IA and IB). Appendix IA applies to communities with local Laboratory Data Management System (LDMS) lab capacity, and Appendix IB applies to communities without local LDMS lab capacity. In addition, participants may be offered coupons to recruit others to join the study. Participants will be compensated if those they recruit participate in the assessment.

Everyone who participates in the assessments will be offered up to two mail-in HIV test kits (or vouchers that can be redeemed for HIV test kits). Participants will be informed that they can give these kits or vouchers to someone else who they feel could benefit from an HIV test. Everyone will also provide blood to determine HIV status, measure HIV viral load, estimate HIV incidence and assess PrEP use. At a subset of communities (i.e., those with local LDMS capacity, see Appendix IA), participants will be asked to provide additional blood for exploratory evaluation of ART and HIV drug resistance; expanded analysis of HIV incidence; HIV phylogenetic analysis (at the post-implementation assessment only); evaluation of other exploratory HIV-related laboratory tests, and tests associated with SARS-CoV-2 or other related viruses. If the participant agrees, a portion of this additional blood sample will be stored and used for additional future laboratory testing. For anyone who tests HIV positive using the mail-in HIV test kit, a protocol will be in place to provide counseling and linkage to local HIV care. The mail-in HIV test kits are provided as a service by the study, and the outcome of the HIV testing will not be captured in the study database.

The questionnaire will be conducted in two parts: 1) a brief computer-assisted self-interview (CASI) and 2) a more detailed online survey. The brief CASI will take place at the same time as the blood draw. Participants will be given the option to complete the online survey at the same time as the blood draw or at a later time. An additional incentive will be provided on completion of the online survey. Should the online survey not be completed at the same time as the blood draw, information on how to access the more detailed online survey and receive compensation will be provided. Limited contact information will be collected for the purpose of providing reminders (text and/or email) for completion of the online survey, as needed.

The brief CASI will collect sociodemographic data, awareness of the study components and for how long the participant has lived in the intervention or SOC community. The content of the longer online survey will cover topics including, but not limited to, multi-level social support, multi-level intersectional stigma (racism, HIV-related and sexual stigmas), structural barriers to healthcare access, and individual level agency, including uptake of HIV and STI testing, PrEP knowledge and use. The types of scales and questions that will be considered in designing the online questionnaire may include the following:

- Multi-level social support: collective efficacy scale (200), sense of community scale (201), social support measures (in-person (202) and online (203))
- Multi-level intersectional stigma: HIV stigma scale (204), gender non-conforming stigma scale (205), sexual stigma scale (206), discrimination scale (207), healthcare climate questionnaire, racial and sexual identity incongruence, internalized racism scale (208),

internalized homophobia (209)

- Structural barriers to healthcare access: accessibility of HIV testing, accessibility of STI testing, PrEP accessibility, accessibility of peer support, accessibility to HIV care and ART
- Individual level agency: perceived competence scale, brief resilience scale (210), self-efficacy scale (211), questions about HIV/STI testing and diagnosis, PrEP knowledge and use, condom use and condom self-efficacy (212, 213), mental health, substance use and peer support

If not everyone who provides a blood sample goes on to complete the longer online survey, the team may decide to recruit others to complete only this aspect of the assessment.

During the assessment, information about residency and broad location (county and/or zip code) will be requested. Limited personal information will be collected to prevent duplicate participation and to provide compensation to those who recruit others to join the study. No unique identifiers will be captured in the study database; however, limited and non-identifying sociodemographic data (age, race, ethnicity, etc.) will be collected.

10.4 Cross-Sectional Assessment Population and Sample Size

The baseline and post-implementation assessment participants will be persons who self-identify as Black man (inclusive of cisgender and transgender men), self-report a lifetime history of sex with other men, are at least 15 years of age, who self-report current residence in the community of interest, and are willing and able to provide informed consent and agree to complete a short questionnaire and provide two blood samples (one by fingerstick and another by venipuncture). HIV status will not be ascertained prior to participation in these assessments and eligible Black MSM may participate regardless of HIV status.

The baseline assessment will include 100 Black MSM from each of the 16 participant communities (intervention and control) for a total of 1600 individuals. The post-implementation assessment will include 200 Black MSM in each of the 16 participating communities (intervention and control) for a total of 3200 individuals.

Note that it is possible that the same individual may participate in both the baseline and post-implementation assessment; however, overlap between the samples is anticipated to be minimal, and the information to determine that an individual has participated in both assessments will not be maintained in the study database. Therefore, no attempt will be made to determine who may have completed both assessments. Even if there is some overlap between the baseline and post-implementation sample populations, the statistical methodology that will be used for the cross-sectional assessments remains valid.

10.5 Participant Discontinuation

Participants who are found to be ineligible after enrollment, or who violate any rules determined for participation during the assessments may be removed from the study. Any rules governing participant conduct during the assessments will be outlined in the SSP.

10.6 Human Subjects Considerations

Individuals participating in the cross-sectional assessments will be considered study participants and will be enrolled into the study. Cross-sectional activities are considered non-exempt human subjects research and 45 CFR 46 Subpart A applies.

10.6.1 Informed Consent

A consent form must be completed before participants undergo any procedures. Templates for the consent form are included in Appendices III and IV. All participants will be offered a copy of their signed consent form.

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian permission will be requested for those 15 to 17 years old. These participants will still be required to provide assent by completing the informed consent process. Staff will be trained to provide additional information to those younger than 18 to ensure that they understand that they are participating in a research study.

10.6.2 Confidentiality

Limited personal information will be collected from participants in order to prevent duplicate participation within each assessment, to provide compensation to those who recruit others into the study, and to send reminders to complete the online survey. This information will be maintained confidentially by those who conduct the assessment in the field. No identifying information will be captured in the study database.

10.6.3 Compensation

Study participants will receive compensation for supplying blood samples, completing the questionnaires, and recruiting others into the study.

11.0 PROVISION OF PRE-EXPOSURE PROPHYLAXIS AND ANTIRETROVIRAL THERAPY

In order to support HIV prevention in Black MSM and to engage both intervention and SOC communities, HPTN 096 will provide PrEP, and potentially ART for HIV treatment, to at least one facility in each community. The study team will work with the local health departments and EHE committees to determine the best facility, which may include virtual PrEP and pharmacies. In the intervention communities, we will choose a facility undergoing the intersectional stigma reduction (CRISP) component. PrEP, and potentially ART for HIV treatment, will be provided to these locations free of charge throughout the entire 3-year implementation period. The study

team will partner with pharmaceutical companies (Gilead, and potentially others) to provide PrEP, and potentially ART, throughout the study. The study will endeavor to provide the most effective and safe option available and will start by providing Descovy, and potentially Biktarvy. However, the specific type of PrEP or ART being provided may change over the course of the study and may include more than one option. It is our intention to also provide long-acting injectable Cabotegravir (CAB-LA) if/when it becomes commercially available. The study will seek support for any laboratory testing required for PrEP acquisition; however, even if the study cannot provide this type of support, free or low-cost options may be available through ongoing EHE efforts. Any facility chosen to receive and distribute study-provided PrEP or ART will be fully capable of managing, prescribing and providing clinical oversight for PrEP or ART. After the study ends, these communities will continue to have access to free and/or reduced cost PrEP or ART via local EHE efforts. The HPTN 096 SSP Manual will outline the mechanism for PrEP and ART provision.

12.0 STATISTICAL CONSIDERATIONS

12.1 Review of Study Design

This community randomized trial will evaluate the effectiveness of an integrated strategy to increase levels of viral suppression in Black MSM living with HIV and increases levels of PrEP use in Black MSM living without HIV. Communities will be paired based on preliminary information on rates of viral suppression and other demographic information. The integrated strategy components will be delivered for three years, and the impact will be measured using CDC surveillance data on viral suppression among individuals living with HIV and cross-sectional assessments evaluating PrEP use among individuals living without HIV.

12.2 Endpoints

12.2.1 Primary Endpoints

- Consistent with the primary study objective to increase the proportion of Black MSM living with diagnosed HIV who are virally suppressed (<200 copies/mL), the following endpoint(s) will be assessed:
    - (primary) The ratio of the number of Black MSM living with diagnosed HIV who are virally suppressed (<200 copies/mL) as measured by HIV surveillance data divided by the number of Black MSM living with diagnosed HIV as measured by HIV surveillance data
    - (supportive) HIV viral load measured in a cross-sectional post-implementation assessment

- Consistent with the primary study objective to increase PrEP use by Black MSM not living with HIV, the following endpoint(s) will be assessed:
    - (primary) The presence of PrEP agents measured in a dried blood spot (DBS) during the post-implementation cross-sectional assessment

- (supportive) The ratio of the number of Black men with PrEP prescriptions (from AIDSVu) divided by the number of Black men with PrEP indications (from CDC)

12.2.2 Secondary Endpoints

- Consistent with the secondary objective to compare self-reported HIV testing behavior in Black MSM in the intervention communities to the SOC communities at the end of the three-year integrated strategy based on the post-implementation cross-sectional assessment
  - Responses to survey questions collected during the post-implementation cross-sectional assessment

- Consistent with the secondary objective to compare social support, intersectional stigma, barriers to healthcare, and individual agency in Black MSM in the intervention to the SOC communities at the end of the three-year integrated strategy based on the post-implementation cross-sectional assessment
  - Responses to survey questions collected during the post-implementation cross-sectional assessment

- Consistent with the secondary study objective to increase the proportion of Black MSM living with newly diagnosed HIV in the past year who are virally suppressed (<200 copies/mL) within six months of diagnosis, the following endpoint will be assessed:
  - The ratio of the number of Black MSM with HIV newly diagnoses in Year 3 who have a suppressed VL within six months of diagnosis as measured by HIV surveillance data divided by the number of Black MSM with HIV newly diagnosed in Year 3 based on HIV surveillance data

- Consistent with the secondary study objective to track ongoing EHE implementation activities for Black MSM
  - Information about EHE implementation activities affecting Black MSM in the EHE plans of all intervention and control communities, as well as additional information from local health departments and EHE committees

- Consistent with the secondary study objective to assess measures of care quality, and care responsiveness to Black MSM needs at HCFs participating in the CRISP component, pre- and post-implementation
  - Self-reported survey data from health care workers who participate in the CRISP component
  - Aggregated, facility-level independent ratings of HCF workers

- Self-reported survey data from Black MSM receiving services at HCFs participating in CRISP activities

12.3 Sample Size

The primary outcomes of the proposed study are viral suppression among Black MSM living with HIV and PrEP use among Black MSM living without HIV.

Viral suppression will be measured through the CDC surveillance system that measures viral suppression among all diagnosed individuals living with HIV in a given community. Preliminary data from 2017 in the 20 communities under consideration for HPTN 096 show that the average viral suppression in Black MSM is 56.7% and the between-community standard deviation is 7.0%. Since the CDC surveillance data include all known MSM living with HIV (i.e. a census) we assume there is no within-community variance. Further analysis of the proposed pairs yields an estimated intraclass (intrapair) correlation of 0.41. Table 5 shows the minimum detectable difference with 90% power between the intervention and control arms for unpaired and paired community randomized trial designs with varying numbers of communities.

Table 5: Minimum Detectable Difference in Percent Viral Suppression Between Arms with 90% Power Using $\alpha = 0.05$ (two-tailed) and Intrapair Correlation of 0.41*

Communities per arm	Unpaired	Paired
6	14.5	12.5
8	12.2	10.2
10	10.7	8.8

*Exact t distribution is used for quantiles.

We believe an improvement of 10 percentage points in average percent suppressed (e.g., from 57% to 67%) is achievable with the proposed integrated strategy and so we propose a paired community randomized trial with 8 pairs. We also note that including baseline (pre-implementation) rates of viral suppression in the analysis may increase power by reducing unexplained variation in the analysis.

PrEP use will be measured in a cross-sectional sample of Black MSM from each community at the end of the three-year implementation period using starfish sampling. Blood samples will be collected from each participant to assess HIV infection status and, in participants living without HIV, PrEP use (in DBS). As shown in Table 6, we make the following assumptions in our sample size calculations:

- 200 Black MSM surveyed in each community.
- Samples includes 30% MSM living with HIV and 70% MSM living without HIV (justification: HPTN 078 found 30% HIV-positive using a similar sampling strategy in similar locations. CDC data on numbers of HIV diagnoses in Black MSM in the EHE counties suggest HIV prevalence among Black MSM around 30%).
- 10-20% effective PrEP use among Black MSM living without HIV in SOC communities. This is higher than current levels, but PrEP use is increasing over time and this is believed to be a reasonable estimate of PrEP use by the time this study starts.

- Type 1 error rate = 5% (two-sided); Power = 90%.

Table 6: Minimum Detectable Risk Difference (increase in PrEP use from baseline) with 90% Power Assuming at Least 140 At-risk Black MSM living without HIV per County, 8 Communities per Arm (paired design), alpha = .05, two-sided*

Baseline PrEP use	Paired coefficient of variation (CV)			
	.10	.15	.20	.25
10%	.059	.067	.077	.091
15%	.071	.084	.101	.122
20%	.082	.100	.123	.153

* Exact t distribution is used for quantiles.

In previous studies of HIV incidence, the CV in paired trials has been around 0.15, although it is unclear how those results apply to the endpoint of PrEP use. In addition, we will have baseline measurements from a similarly designed survey (albeit with only 100 Black MSM per community) that will be included in the analysis (see Section 12.8) and may increase power. Thus, based on the proposed design we will have at least 90% power to detect an increase in PrEP use of 15 percentage points over all scenarios, and the minimum detectable increase is lower for most scenarios. This level of improvement in PrEP use is a reasonable target for HPTN 096.

12.4 Accrual and Retention

A total of 16 communities will be enrolled in HPTN 096. In each community cross-sectional samples of 100 Black MSM will be recruited at baseline using starfish sampling and 200 Black MSM will be recruited at the end of the study using starfish sampling. There is no longitudinal follow up in HPTN 096, therefore there is no retention target.

12.5 Random Assignment/Study Arm Assignment

Prior to randomization communities will be paired based on demographics (community size and percent of the population that are Black) and baseline rates of viral suppression and PrEP use (based on CDC data). Within each pair one community will be randomized to the integrated strategy and one will be randomized to the SOC. Randomization will take place in a public ceremony.

12.6 Blinding

It is not possible to blind the investigators, study personnel or participants to the community intervention arms. However, interim reports and results on post-baseline data for the primary endpoints will only be presented in aggregate form.

12.7 Study Monitoring and Interim Analyses

Data and Safety Monitoring Board oversight is not planned for this study. The HPTN SMC will conduct interim reviews of study progress, including rates of participant accrual for cross-sectional assessments, measures of integrated strategy delivery and uptake (i.e., process measure

data), and completion of primary and secondary endpoint collection. The frequency and content of HPTN SMC reviews will be determined prior to the start of the study as outlined in the HPTN Manual of Operations (MOP).

In addition, we will conduct a formal interim analysis halfway (approximately 18 months) into the intervention period. Monitoring guidance will be detailed in a separate Interim Monitoring Plan. The HPTN SMC will conduct this formal review and make a recommendation regarding study continuation.

12.8 Statistical Analysis

This section briefly describes the final study analyses. Detailed technical specifications of the statistical analyses will be described in a separate Statistical Analysis Plan.

12.8.1 Controlling for EHE activities and other external factors

Concurrent with the study activities we expect ongoing EHE activities to increase testing, viral suppression and PrEP use in all study communities. There may be variability in the intensity of these EHE activities from community to community. While a key benefit of randomization is to balance the effect of such external activities between the study arms, it is possible that in a trial with a relatively small number of randomization units (communities), that imbalances may result by chance. To control for this possibility we propose developing a propensity score (214) by fitting a logistic regression model to predict study arm (outcome) as a function of various measures of EHE activities (see section 9.0) and other external factors (e.g. availability of CAB-LA for PrEP) that may affect the primary outcomes and be differentially distributed across the study communities. The propensity score will then be included, along with the intervention arm, in the various primary and secondary analyses described below. Note that only EHE activities that are completely external to the current trial will be included as part of the propensity score.

12.8.2 Primary Analyses

This trial is designed to separately address the effect of the intervention on (i) viral suppression and (ii) PrEP uptake. As these are two distinct scientific questions, no adjustment for multiple testing is proposed.

12.8.2.1 Viral Suppression

Our primary measure of viral suppression rates among Black MSM in the participating communities will be based on CDC surveillance data. Viral suppression in the CDC data is based on the last viral load measurement in the calendar year (if there are more than one) and individuals with missing viral loads are assumed to be not suppressed. The viral suppression rates for all participating communities will be reported. A weighted mean viral suppression rate (weighted by number of diagnosed Black MSM living with HIV in the community) will be used to summarize suppression rates by arm. Specifically, the estimated viral suppression for arm A is

$$\sum_{i,j:j\in A} \frac{n_{ij}}{n_A} V_{ij} \quad (1)$$

where V_{ij} is the viral suppression rate in community j in pair i, n_{ij} is the number of diagnosed Black MSM living with HIV in community i in pair j and $n_A = \sum_{i,j\in A} n_{ij}$. The difference in the (weighted) suppression rates between arms will be used to measure the intervention effect. To estimate and test for an intervention effect, we will fit a linear regression of the following form using "analytic weights", $w_{ij} = n_{ij}$:

$$V_{ij} = \mu + \eta_i + \Delta X_{ij} + \beta_1 B_{ij} + \beta_2 S_{ij} + \epsilon_{ij} \quad (2)$$

where μ is the overall mean, η_i is a fixed effect for pair i, X_{ij} is an intervention indicator, Δ is the intervention effect, B_{ij} is the viral suppression rate at baseline, S_{ij} is the propensity score, and ε_{ij} captures the within-pair, between-community variation. Since the CDC surveillance data represent a complete census of diagnosed HIV-positive individuals, the within-community variation in V_{ij} is assumed to be zero, although this assumption has no practical impact since the within and between community variance components cannot be separately estimated with this design. Note that if all community sizes are equal ($n_{ij} = n$) and the baseline rates and propensity score are not included, then this approach is equivalent to a paired t-test on the community level viral suppression rates. We will provide a 95% CI for Δ from the post-implementation period and a p-value for testing the hypothesis Ho: $\Delta = 0$ using $\alpha = 0.05$ (two-sided) for the post-implementation data. We will also provide viral suppression rates and estimates and CI for Δ for each year during the implementation period to understand the change in the intervention effect over time.

Since the above analysis depends on model assumptions, we will also conduct a paired t-test on the (unweighted) change from baseline in each community as a sensitivity analysis.

Additional supportive data on viral suppression may be available from the samples of men living with HIV participating in the cross-sectional surveys. Note that these surveys can potentially capture both diagnosed and undiagnosed men with HIV, in contrast to the CDC surveillance data that captures only men with diagnosed HIV. The percent of Black MSM living with HIV who are virally suppressed will be computed from the post-implementation cross-sectional sample for each community and reported. The average suppression by arm will be computed as the weighted mean of the community percentages, as in equation (1). A 95% confidence interval on the percent viral suppression will be reported by arm.

We will use a weighted regression analysis (with analytic weights, $w_{ij} = n_{ij}$, the estimated number of Black MSM living with HIV in community j in pair i) to estimate the treatment effect while adjusting for baseline viral suppression as in equation (2) above. We will test the hypothesis Ho: $\Delta = 0$ ($\alpha = 0.05$, two-sided) and provide an estimate of Δ and 95% CI in this secondary evaluation of the intervention effect on viral suppression.

12.8.2.2 PrEP Use

Our primary measure of PrEP use will be PrEP measured in DBS samples at both the baseline and the post-implementation community surveys. Since all communities will target the same

sample size (though different between baseline and post-implementation assessments) the number of individuals living without HIV surveyed will be approximately the same across all communities within a given survey period. The percent of Black MSM living without HIV with any detectable PrEP will be computed for each community at each time point and reported. The average PrEP use by arm will be computed as the weighted mean of the community percentages:

$$\sum_{i,j:j\in A} \frac{n_{ij}}{n_A} P_{ij} \quad (3)$$

where P_{ij} is the post-implementation PrEP use percent in community j in pair i, n_{ij} is the estimated number of Black MSM living without HIV with PrEP indications in community i in pair j and $n_A = \sum_{i,j\in A} n_{ij}$. The n_{ij} will be based on a tool developed by CDC – see http://tinyurl.com/PrEPWebtool).

We will use a weighted regression analysis to estimate the treatment effect while adjusting for baseline PrEP use with analytic weights equal to the estimated number of Black MSM living without HIV with PrEP indications in the community (n_{ij}). The model will be

$$P_{ij} = \mu + \eta_i + \Delta X_{ij} + \beta_1 B_{ij} + \beta_2 S_{ij} + \epsilon_{ij} \quad (4)$$

where P_{ij} is the post-implementation PrEP use percent in community j in pair i, B_{ij} is the baseline PrEP use percent, S_{ij} is the propensity score, and other parameters are as described in Section 12.8.1.1. Note that this analysis is equivalent to a paired t-test if the analysis is unweighted and baseline rates and the propensity score are not included. We will test the hypothesis Ho: $\Delta = 0$ ($\alpha = 0.05$, two-sided) and provide an estimate of Δ and 95% CI to evaluate the intervention effect on PrEP use.

Since the above analysis depends on model assumptions, we will also conduct a paired t-test on the (unweighted) change from baseline in each community as a sensitivity analysis.

A supportive analysis of PrEP use will be based on prescription drug data. AIDSVu is an Emory database that provides data on the (estimated) number of Black male PrEP users by county (at this time the data are not available by risk group) (215). Further, the CDC has developed a tool to estimate the number of persons with PrEP indications (216). These data are available by sex, age, and race and will soon be available at the county level. We will compute the ratio of Black Male PrEP users divided by Black men with PrEP indications in each community. The average ratio, weighted by the number of Black men, in the control and intervention communities, along with 95% confidence intervals, will be reported.

We will use a weighted regression analysis (weights equal to the number of Black men with PrEP indications) to estimate the treatment effect on this PrEP use ratio while adjusting for baseline PrEP prescription use and propensity score as in equation (4) above. We will test the hypothesis Ho: $\Delta = 0$ ($\alpha = 0.05$, two-sided) and provide an estimate of Δ and 95% CI in this secondary evaluation of the intervention effect on PrEP prescription use.

12.8.3 Secondary Analyses

12.8.3.1 Self-reported HIV testing behavior

Information on recent HIV testing will be collected from all individuals participating in the baseline and end of study surveys. We will report the proportion of Black MSM living without HIV who self-report being tested for HIV within the prior year in the surveys from each community. We will use a weighted regression analysis, similar to equation (4) above, to estimate the intervention effect on testing in the end of study surveys after adjusting for baseline testing percentage, propensity score and community pair.

12.8.3.2 Social Support, Intersectional Stigma, Barriers to Healthcare and Individual Agency

These measures will be collected as part of the longer online survey that we will seek to obtain from all individuals in the baseline survey and the end of study survey. Intersectional stigma is also measured on HCFs in each community. For each outcome, we will use a weighted regression analysis (with analytic weights, $w_{ij} = n_{ij}$, the estimated number of Black MSM in community j in pair i) to estimate the intervention effect while adjusting for the baseline measure and propensity score as in equation (2) above. We will test the hypothesis Ho: $\Delta = 0$ ($\alpha = 0.05$, two-sided) and provide an estimate of Δ and 95% CI of the intervention effect on social support, intersectional stigma, barriers to healthcare, and individual agency.

12.8.3.3 Time to Viral Suppression

This analysis will be similar to the primary analysis described in Section 12.8.2.1. However, the analysis will be restricted to Black MSM diagnosed in the past year. The outcome will be percent of Black MSM diagnosed in the past year who are virally suppressed within 6 months after diagnosis, based on CDC surveillance data. We will compute a weighted estimate of percent suppressed by arm, similar to equation (1), and use a weighted regression analysis controlling for baseline and propensity score, similar to equation (2), to estimate the intervention effect, provide a 95% confidence interval and test the hypothesis Ho: $\Delta = 0$ using $\alpha = 0.05$ (two-sided). A sensitivity analysis using 12 months after diagnosis window will also be conducted.

12.8.3.4 Tracking ongoing EHE implementation activities

We will summarize ongoing EHE activities by county and provide descriptive comparisons between intervention and control communities.

12.8.3.5 Assess measures of intersectional stigma, care quality, and care responsiveness

We will assess intersectional stigma, care quality and care responsiveness based on pre and post (CRISP) participation surveys in health care facilities in the intervention communities. To assess intersectional stigma among HCF workers, we will conduct a pre-post assessment of HCF workers who participated in CRISP. Building on the work currently underway in an active NIH sponsored trial of intersectional stigma reduction led by one of the protocol co-chairs (R01 NR019009-01, PI: Nelson), we propose to measure intersectional stigma as a latent variable derived from three manifest variable measures that assess the different stigmas targeted in this study. These measures include: (217) HIV Stigma and Discrimination among Health Facility

Staff Questionnaire, (218) LGBT Phobia, Attitudes and Cultural Competence Scale, and (219) Gender Equitable Men Scale. Confirmatory factor analysis will be used to identify items that cluster together from each of the individual measures to represent the latent measure of intersectional stigma. We will train Black MSM as independent raters ("client-instructors") who can assess the presence of intersectional stigma in healthcare facilities—both its structural and procedural manifestations as well as the interpersonal manifestations. These independent ratings data would then be triangulated with the HCF worker self-assessments to characterize intersectional stigma at baseline and post-implementation at the facility level. Anonymous client surveys will be assessed for care quality and responsiveness.

We will summarize responses by facility pre- and post-implementation. We will provide a statistical comparison of results by fitting an appropriate regression model (depending on the nature and scale of the outcome measure) with a fixed effect for period (pre vs post) and random effects for facility nested within community. We will also include a facility*period (random) interaction term to account for the fact that the intervention effect may vary by facility. Any additional measured factors that may lead to confounding in the pre-post analysis will also be included in the model. We will provide an estimate of the adjusted period effect along with a 95% confidence interval.

12.8.4 Attribution Analysis

There will be variation in the delivery of the various components of the intervention across the eight intervention communities. We will combine this natural variation within the intervention arm with the designed variation between the randomization arms to estimate the contribution made by each of the integrated strategy components (health equity, social influencers, intersectional stigma reduction, and peer support) to changes in viral suppression and PrEP use. Sections 5.5, 6.5, 7.5 and 8.5, respectively, describe the process measures of health equity, social influencers, intersectional stigma reduction, and peer support that will be collected in the intervention communities. We will use a factor analysis (or other summary) of the multiple measures collected for each component to create a single summary score for each component. We will then regress these four summary scores (with a score of zero for control communities) against each outcome. The partial R^2 statistic will be used to quantify the proportion of variation in the outcome that can be attributed to each intervention component summary.

13.0 SOCIAL HARMS REPORTING

It is possible that some elements of the study may result in a social harm. A social harm is defined as an undesired change in a person's relationships, experiences, interactions, rights and/or community status that occurs as a direct result of participating in a research study. For the four integrated strategy components, no study participants will be enrolled into the study, have identified data collected or be followed longitudinally. However, it is conceivable that there may be negative impacts from components of the integrated strategy; for example, if a family member saw someone interacting with the virtual peer support platform, there could be negative repercussions. Social harms may also occur to implementers of the integrated strategy components. For example, content that is developed by an SMI for the purposes of the study may cause the SMI to be negatively targeted or bullied by members of their online community.

The study team will be vigilant for evidence of such incidents and will report them to the study database in association with the relevant integrated strategy component but not associated with specific participants or implementers. Implementers will also be instructed on how to report such incidents to the study team – for either themselves or on behalf of others who may have been negatively impacted by the study activities – for documentation in the study database.

It is possible that participation in the cross-sectional assessments may result in a social harm. The cross-sectional assessments will enroll and collect data on individual participants; therefore, social harms will be reported by participant identification number to the study database for this component of the study only. A summary of all social harms will be reported to the single institutional review board (sIRB) at least annually. The protocol team will review the social harms and watch for any trends. If needed, adjustments will be made to study conduct. In addition, the study's community advisory group (CAG) may be consulted to help minimize the potential occurrence of specific types of social harms if trends are discovered.

14.0 HUMAN SUBJECTS CONSIDERATIONS

Human subjects considerations specific to the integrated strategy components and the cross-sectional assessment, including discussions of applicability of 45 CFR 46, are included in each respective component and cross-sectional assessment Sections (Sections 5.4, 6.4, 7.4, 8.4 and 10.5). The following Sections discuss overall human subjects and research ethics considerations applicable to the general study design.

14.1 Collaborative Community Partnerships

Community representatives have been involved in the study design and finalization of the integrated strategy components at all stages of the development of this protocol. The study team will continue to actively engage with the study communities at various levels (for example with local health department and EHE structures, HCFs, existing community forums and stakeholder groups) utilizing a range of communication and interaction strategies, as appropriate. A study CAG will be formed with representation from community stakeholders from all randomizable units, to provide ongoing guidance and feedback to the study team, including but not limited to PrEP, randomization, implementation of the cross-sectional assessments, and operationalization of the integrated strategy (in intervention communities only, to minimize contamination in control communities). A community strategy group will also be utilized, comprised of community representatives and study team members, to direct and oversee the community engagement activities throughout the course of the study.

14.2 Risk-Benefit Assessment

This community randomized study can potentially incur risk of harm at both a community and an individual level. Likewise, study-related benefits may accrue at both an individual and a community level.

14.2.1 Community-Level Benefits

At the community level, an integrated strategy may result in a substantial reduction in HIV incidence among Black MSM. The nature of some HPTN 096 components in attempting to address social determinants of health may provide benefits in sectors beyond the realm of HIV and health, and the components related to SMIs and intersectional stigma prevention may promote acknowledgement and acceptance of HIV as a community-wide health issue potentially resulting in lessening of stigma and discrimination. While the SOC communities will not benefit directly from the integrated strategy, there will be increased access to PrEP in both SOC and intervention communities as a result of this study (per Section 11.0). In addition, if the study shows that the integrated strategy is effective, leading to wider scale roll-out of the program, efforts will be made to ensure that the SOC communities are among the first to benefit from this wider implementation. SOC communities will be most familiar with the integrated strategy and will be engaged throughout the study, leading to a greater likelihood of program adoption and implementation if the strategy is found successful. Relationships forged between researchers, community members, and public health officials by way of this study can provide a more efficient and clearer pathway to post-study implementation in SOC communities. This is particularly true as this study will end in the middle of the EHE initiative, and components of the integrated strategy could be built into ongoing EHE plans depending on the results of the study. Networks of stakeholders that will be created through the implementation of the integrated strategy will not only improve communication between community groups but will also be a catalyst for reinvigorating, reinforcing, and bolstering social connections that can be useful for advocating for the social and health-related needs of Black communities.

14.2.2 Community-Level Risks

Any community-based research project may present risks to a community. For example, communities may feel disempowered by having a research agenda imposed on them or they may be placed at risk of stigmatization by the publication or dissemination of research results. Large community research projects may disrupt intra-community social structures and networks that are not always easily understood by an external research team. Social harms will be measured through collection of social harms data (see Section 13.0). An additional potential community related risk involves the possible burden that could be placed on existing health services. Existing health services in many of these study communities may already be over-burdened and under resourced; these challenges have been exacerbated by the COVID-19 pandemic that begin in early 2020.

14.2.3 Minimizing Risks to Communities

Well-functioning community engagement structures (such as the CAG), as well as formal and intentional representation of Black MSM and community members as part of the study team, will help to mitigate risks at the community level by advising the study team and representing the views of the communities and study populations in all aspects of the design and implementation of the study. The CAG, along with implementers of the integrated strategy (e.g., peer supporters, SMIs), will serve as lenses into the community and can help the study team gauge any potential risk of harm which may occur. In addition, the study team will actively solicit and report any instances of perceived social harm (see Section 13.0).

Working closely with communities and policy makers in the communities (i.e., EHE planning councils) to design and implement the study will also help mitigate risks. Health service burden will be minimized by coordinating efforts with existing EHE planning committee work in each community, leveraging additional funding to further the existing EHE efforts via implementation of this study, and in provision or supplementation of services that would otherwise need to be provided by these over-burdened health systems, such as PrEP, allowing a greater impact of EHE activities and resources. Communication will be maintained with study communities for the duration of the study and a well-developed exit strategy will be planned with the input of all stakeholders and community engagement structures. If proven effective, the HPTN 096 integrated strategy can provide a model for what jurisdictions may wish to adopt to address HIV in Black MSM once the study is complete. Furthermore, some components of HPTN 096 such as the intersectional stigma training curriculum, plans for enhanced activities of the BTAN+ model, peer support app, or the database of local HIV-related and social services could be made available for use by others after the study has ended, including to both intervention and SOC communities.

14.2.4 Individual-Level Benefits

Individual community members will be directly and indirectly impacted by the integrated strategy, though there will be no active enrollment of study participants in any of the integrated strategy components (there will be active enrollment in the cross-sectional assessments). There may be a wide range of benefits at the individual level. Knowledge of one's HIV status provides a portal to treatment and care services for individuals living with HIV, while individuals living without HIV can be supported in adopting preventive measures such as PrEP. Preventing or reducing intersectional stigma, changing social norms around HIV, and fostering supportive peer networks can improve the social and healthcare environments in which individuals exist and receive HIV care and preventive services, as well as provide social and emotional support and advice about how to prevent HIV and what to do in the case of infection.

14.2.5 Individual-Level Risks

Components of the integrated strategy which involve direct interaction with individuals (such as virtual peer support), even if individuals are not enrolled in the study, may involve some risks. These include possible social harms and risks related to disclosure of HIV status or participation in HIV-related research.

For the cross-sectional assessments, there may also be a risk of HIV stigmatization from association with an HIV-related study at sampling venues. Additionally, there are minor risks associated with blood draws.

Individuals interacting with these study components will be informed of these risks, which are detailed in their respective informed consent forms (ICFs) in Appendix II, III and IV. Social harms will be captured per Section 13.0.

14.2.6 Minimizing Risks to Individuals

To minimize social and other harms to individuals, the study team will train implementers (and their supervisors) who deliver virtual peer support and training in the CRISP component in cultural humility, as well as skills to provide HIV-related counseling according to national guidelines and to ensure that confidentiality is protected. No individual-level identifying information will be collected by the study team or implementers within any study component for research purposes. Additionally, the HPTN, under the NIH, has a Certificate of Confidentiality from the US Department of Health and Human Services that is applicable to this study. Certificates cover all study staff conducting this research, regardless of the country where the investigator or the protected information resides. This Certificate protects study staff from being compelled to disclose study-related information by any Federal, State or local civil, criminal, administrative, legislative, or other body.

For the cross-sectional analyses, data systems and data handling procedures for capturing, transferring, analyzing and storing electronic data obtained from sampling venues will be developed and tested to verify their ability to preserve participant confidentiality. Electronic systems in which these data are kept will be password protected with access limited to authorized staff. Personal identifiers (e.g., name, address, birthdate) may be collected by study staff for the purposes of ensuring dual enrollment does not occur and to provide compensation to those who successfully recruit others to join the study; however, no identifying information will be retained in electronic data capture systems or the study database. Participant identification numbers will be assigned to each cross-sectional assessment participant to uniquely identify data and samples collected. All study staff engaging in venue-based sampling activities will undergo training in Good Clinical Practice and human research protections in accordance with NIH requirements. There will be a strong emphasis in staff training and supervision on the importance of strict confidentiality of participant information, and systems will be in place to ensure that any personal information is securely stored within locked containers. Blood collection will be carried out by fully trained staff using appropriate sterile procedures.

14.3 Ethical Review

The HPTN Ethics Working Group developed the Ethics Guidance for Research, a network-wide ethical principles document, which is suitable for further elaboration and tailoring for each study.

This protocol and the template ICFs contained in Appendices I-III will be reviewed and approved by the HPTN Scientific Review Committee and NIAID Prevention Science Review Committee with respect to scientific content and compliance with applicable research and human subjects regulations.

The protocol, ICFs, participant education and recruitment materials, and other requested documents — and any subsequent modifications — also will be reviewed and approved by the HPTN single IRB (sIRB). The HPTN Leadership and Operations Center (LOC) will make progress reports to the sIRB at least annually, and within three months of study termination or completion.

14.3.1 Additional Considerations for Minors

Adolescents aged 15 years and older are eligible to participate in the virtual peer support component and the cross-sectional analysis. Per the US Code of Federal Regulations (CFR), the HPTN sIRB must consider the potential risks and benefits to these participants as described in 45 CFR 46 Subpart D.

With respect to 45 CFR 46 Subpart D, the specifications of 45 CFR 46.404 are expected to apply to adolescent participants not of legal age to consent in both the virtual peer support component and the cross-sectional assessment. These study components will not involve investigational drugs or devices, nor will either individual (for the peer support component) or identifying (for the cross-sectional assessments) data be collected; thus, the study involves no more than minimal risk to any participant.

Per 45 CFR 46.408(a), it is expected that adolescents participating in this study would be deemed capable of providing assent. Specific assent considerations for this population are described in the component-specific sections 8.4.1 and 10.5.1. However, per 45 CFR 46.408(c), this study is designed for a population (Black MSM in the southern US) for which parental or guardian permission is not a reasonable requirement to protect the study participants. There is concern that parent/guardian knowledge of a participant's involvement in the study may pose significant risk to participant's privacy and confidentiality, particularly for those whose parents are not aware or supportive of their sexual orientation, and stigma may prevent these adolescents from participating in the study. As such, a waiver of parental/guardian permission will be requested from the sIRB. Maintaining the requirement for assent will serve as a mechanism to protect these adolescents, in combination with additional counseling that will be provided to this age group as described in the above-referenced component-specific protocol sections.

It is the responsibility of the HPTN sIRB to determine the level of risk to adolescents in the categories specified in 45 CFR 46.404-407. The risk category assigned by the sIRB will ultimately determine the parental informed consent and assent requirements for the study. Additionally, it will be the responsibility of the sIRB to require any additional mechanisms to protect adolescent participants in lieu of parent/guardian consent, per the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual: Informed Consent of Participants: https://www.niaid.nih.gov/sites/default/files/score-informed-consent.pdf.

14.4 Informed Consent

Individual informed consent considerations that are specific to each study component and the cross-sectional assessments are detailed in each of those respective protocol Sections (Sections 5.4.1, 6.4.1, 7.4.1, 8.4.1, and 10.5.1).

14.5 Study Discontinuation

The study may be discontinued at any time by NIAID, the HPTN, and/or the sIRB.

15.0 LABORATORY SPECIMENS AND BIOHAZARD CONTAINMENT

Laboratory procedures are described below and in Section 10.0 (Cross-Sectional Assessments).

15.1 Local Laboratory Specimens

Local laboratories will be used to process blood samples for the cross-sectional assessments. Any entity collecting samples for the cross-sectional assessment (e.g., mobile vans, clinics, laboratories, etc.) and all local laboratories should reference the HPTN MOP, the SSP Manual, and local Standard Operating Procedures for proper collection, processing, labeling, transport, and specimen storage. The Requirements for DAIDS Funded and/or Sponsored Laboratories in Clinical Trials Policy must be adhered to as appropriate. Specimen processing and storage at the local laboratories will be documented using the LDMS as described in the SSP Manual for all specimens collected for the cross-sectional assessment.

15.2 Laboratory Center Specimens

As described in Section 10.0 (Cross-Sectional Assessments), blood will be collected for testing at the HPTN Laboratory Center (LC) or at laboratories designated by the HPTN LC.

15.3 Specimen Storage at Local Laboratories

Plasma and DBS will be stored at local laboratories in a subset of communities until the end of each assessment period (baseline and post-implementation). The HPTN LC will instruct these local laboratories to ship the samples to the HPTN LC once all samples have been collected, processed, and entered into LDMS. A subset of the stored samples will be used by the HPTN LC for quality assurance (QA) and other assessments. Testing on stored samples will be performed by the HPTN LC or other laboratories selected and approved by the HPTN LC. Samples stored at local laboratories may not be used for any testing without written approval by the HPTN LC prior to use. Stored samples will be maintained at the HPTN LC until at least one year after acceptance of the manuscript that describes the primary findings for the study, and after protocol-related testing has been completed. This includes retrospective testing performed at the HPTN LC and laboratories designated by the HPTN LC that is needed to address study objectives. Local laboratories may not destroy samples without written permission from the HPTN LC. The HPTN LC will communicate with local laboratories if and when samples can be destroyed; local laboratories will follow local laboratory policies for sample destruction. The HPTN LC will follow internal sample destruction policies for long-term sample storage. As needed, a list of samples to be destroyed will be provided by the HPTN Statistical and Data Management Center (SDMC), which will be reviewed and reconciled by the local laboratories or HPTN LC as part of the sample destruction process.

15.4 Virology

HIV diagnostic and viral load testing will be performed at a commercial laboratory (all communities). Additional retrospective testing will be performed using stored DBS (all communities) and plasma (subset of communities). This testing will be performed at the HPTN LC or laboratories designated by the HPTN LC. This testing may include the following tests: HIV resistance testing, cross-sectional HIV incidence testing, phylogenetic analysis of viral

sequences (post-implementation assessment only), tests to characterize HIV viruses and/or the host response to HIV infection; and tests associated with SARS-CoV-2 and other related viruses. Results will not be returned to the local laboratories or study participants. This testing may be performed during the study or at the end of the study.

15.5 Pharmacology

DBS samples for pharmacology testing related to PrEP use will be collected during the study from all participants in the cross-sectional assessments; plasma samples will be available from participants at a subset of communities. DBSs are currently used only for the detection and/or quantification of intraerythrocytic tenofovir-diphosphate, to monitor/assess adherence and /or use of TDF/FTC (Truvada) and TAF/FTC (Descovy) PrEP. Plasma can also be used to assess adherence and/or use of these drugs. The window period for detection of drugs is different with DBS and plasma testing (DBS has a longer window period, plasma tests for more recent use).

DBS testing to assess use of TDF/FTC and TAF/FTC PrEP will be performed for all participants living without HIV; plasma testing to assess use of TDF/FTC and TAF/FTC PrEP may be performed in a subset of these participants. If long-acting injectable cabotegravir or other PrEP agents become available during the course of the study, DBS collected from all participants, and the plasma collected from a subset of participants, could also be used to detect these drugs. Procedures for sample processing and shipping are outlined in the SSP Manual. Pharmacology testing will be performed at the HPTN LC or a laboratory selected and approved by the HPTN LC. The primary pharmacologic assessments will be performed using assays that have been validated and approved by the Clinical Pharmacology Quality Assurance Committee.

Results will not be returned to the study participants. Interpretation of pharmacologic results will be led by the HPTN LC Pharmacology Core, in collaboration with other groups, as needed.

Plasma samples from people living with HIV in a subset of communities will also be tested for the presence of antiretroviral drugs using a multi-drug qualitative assay. Results of this testing will not be returned to the study participants.

15.6 Quality Control and Quality Assurance Procedures

Any entity used to conduct HIV diagnostic testing and/or viral load testing for the cross-sectional assessment (Section 10.0) will document that they are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-certified) and/or participate in DAIDS-sponsored external quality assurance programs. Laboratories must also follow the DAIDS requirements (link to policy on DAIDS website https://www.niaid.nih.gov/research/daids-clinical-research-laboratory-specimens-management).

HPTN LC staff may conduct periodic visits to the local laboratories conducting the cross-sectional assessments to review the implementation of on-site laboratory quality control (QC) procedures, including proper maintenance of laboratory equipment and use of appropriate supplies and reagents. HPTN LC staff may also conduct periodic visits to other entities performing laboratory activities as part of the cross-sectional assessments. HPTN LC staff will follow-up directly with site staff to resolve any QC or QA problems identified through

proficiency testing or visit reviews. Throughout the course of the study, the HPTN LC will select a random sample of stored specimens to test for QA purposes. HPTN LC staff will follow-up directly with study staff to resolve any QA problems identified through this process.

HIV diagnostic tests will be listed by the entity conducting the cross-sectional assessment on the lab information sheet and will be subject to review and acceptance by DAIDS and the HPTN LC.

The HPTN LC may perform HIV diagnostic testing for QC to confirm the results of testing done in a subset of communities for the cross-sectional assessments.

15.7 HIV Diagnostic Testing

In the cross-sectional assessments, mail-in HIV test kits or vouchers for such kits will be offered by study staff to all participants. For anyone (inclusive of individuals who receive a test kit from a study participant but who are themselves not enrolled) whose mail-in HIV test kit result is reactive or indicates infection, a protocol will be in place to provide counseling and linkage to local HIV care.

15.8 Long-Term Local Specimen Storage and Possible Future Research Testing

Local laboratories are required to provide short-term storage for all plasma and DBS specimens collected in this study as part of the cross-sectional assessments. Specimens will be transferred to the HPTN LC for testing and storage. Samples in long-term storage may be available for future research testing by the HPTN LC or other interested investigators, in accordance with HPTN policies for Ancillary Studies. Study participants will be asked to provide written informed consent for specimens to be stored long-term for possible future testing. Specimens from participants who do not consent to long-term storage and future testing will only be used for testing that is needed to address protocol objectives.

15.9 Biohazard Containment

As the transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions will be employed by all personnel in the drawing of blood and shipping and handling of all specimens for this study, as currently recommended by the US CDC. All specimens will be shipped using packaging that meets requirements specified by the International Air Transport Association Dangerous Goods Regulations for UN 3373, Biological Substance, Category B, and Packing Instruction 650.

16.0 ADMINISTRATIVE PROCEDURES

16.1 Protocol Registration

There will be no protocol registration requirements for this study because it does not include an investigational agent. There will be no medically-related adverse event collection and will not undergo traditional monitoring.

16.2 Study Activation

The clinics that participate in the CRISP component will undergo an abbreviated site activation process, during which they will submit required documents and put processes into place to prepare for implementation of CRISP. The HPTN LOC will "activate" each clinic after it completes the site activation process. Study implementation may not be initiated until a study activation notice is provided to the site by the HPTN LOC. In addition, if study activation is determined to be necessary for any subsequent amendments, study implementation may not be initiated until a study activation notice is provided to the clinic by the HPTN LOC.

16.3 Study Coordination

Study implementation will be directed by this protocol as well as the SSP Manual. The SSP Manual will outline procedures for each component of the integrated strategy; how data will be captured and processed; social impact assessment, management and reporting; intervention oversight and monitoring; and other study operations.

For the cross-sectional assessments, study case report forms (CRFs) and other study instruments will be developed by the protocol team and HPTN SDMC. Data will be submitted to the HPTN SDMC for cleaning, reporting, and analysis. Quality control data queries will be generated on a routine schedule for verification and resolution by local data management staff.

Close coordination between protocol team members will be necessary to track study progress, respond to queries about proper study implementation, and address other issues in a timely manner. Rates of engagement, for example the number of people participating in the peer support component, the number of staff trained in the intersectional stigma reduction component, and the reaction to social media influencers, will be monitored closely by the team as well as the HPTN SMC.

16.4 Study Monitoring

Because there will be minimal data collected via CRFs, no long-term follow-up of individual participants and the components of the integrated strategy are all considered to be low risk, no traditional monitoring will take place for the study. However, oversight will be provided for each component, including, but not limited to, monitoring the process measures, routine protocol team monitoring of component engagement, and HPTN SMC review. The HPTN LOC, HPTN LC, DAIDS and their designees may visit the clinics that participate in the CRISP component or the entities that conduct the cross-sectional assessments.

16.5 Protocol Compliance

The study will be conducted in full compliance with the protocol. The protocol will not be amended without prior written approval by the Protocol Chairs and DAIDS Medical Officer. All protocol amendments must be submitted to and approved by the sIRB and the DAIDS Regulatory Support Center prior to implementing the amendment.

16.6 Study Records

All study records will be maintained and stored in a secure, complete and accurate manner throughout the study. The responsible parties are outlined below:

- sIRB-related documentation and approval: HPTN LOC
- Health equity component: HPTN LOC, BAI and BTANs
- Social media influencers component: HPTN LOC
- CRISP component: HPTN LOC, contracted training team, and the participating clinics
- Virtual peer support component: HPTN LOC
- Cross-sectional assessments: HPTN LOC, HPTN LC, HPTN SDMC and the entities conducting the cross-sectional assessments

Under the US DHHS regulations, the responsible parties are required to retain all study records relating to research for at least three [3] years after completion of the research, or longer if needed to comply with local regulations.

Completion of a clinical research study occurs when the following activities have been completed:

- All research-related interventions or interactions with human subjects (e.g., when all subjects are off study);
- All protocol-required data collection of identifiable private information described in the sIRB-approved research plan;
- All analysis of identifiable private information described in the sIRB-approved research plan;
- Primary analysis of either identifiable private or de-identified information.

Study records include administrative documentation — including all reports and correspondence relating to the study — as well as documentation related to each participant screened and/or enrolled in the study — including ICFs, locator forms, CRFs, notations of all contacts with the participant, and all other source documents.

All study records (including participant records) may be reviewed by study staff and other staff employed by the HPTN, NIH, Advarra and the US Office for Human Research Protections.

16.7 Use of Information and Publications

Publication of the results of this study will be governed by the HPTN MOP. Any presentation, abstract, or manuscript will undergo review by the HPTN Manuscript Review Committee, and DAIDS prior to submission.

16.8 ClinicalTrials.gov

This protocol is not subject to the Food and Drug Administration Amendments Act of 2007. However, it will be registered in ClinicalTrials.gov to meet International Committee of Medical Journal Editors requirements and as a requirement of the sponsor.

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APPENDIX IA: SCHEDULE OF EVALUATIONS AND PROCEDURES (Local LDMS)

Communities that have a local LDMS Laboratory

Procedures	Baseline (Month 0) Intervention and SOC communities	Post implementation (Year 3) Intervention and SOC communities
Administrative and Behavioral Evaluations/Procedures		
Informed Consent	X	X
Eligibility Assessment	X	X
PTID Assignment	X	X
Limited Contact/Locator Information	X	X
Coupon Disbursement (for RDS)	X	X
Reimbursement Provision	X	X
Social Harm Assessment	X	X
CASI Assessment (including demographics)	X	X
Provision of link to online survey	X	X
Counseling		
Offer condoms, lubricant, prevention materials	X	X
Clinical Evaluations/Procedures		
Fingerstick collection of dried blood spots (DBS)	X	X
Blood collection for HIV and viral load testing[a]	X	X
Blood collection for plasma storage[a]	X	X
Ship blood samples to the commercial lab for testing[b]	X	X
Transfer DBS and blood samples to the local LDMS laboratory	X	X
Provision of mail-in HIV test kit or voucher (if desired)	X	X
Laboratory Evaluations/Procedures (Commercial)		
HIV testing[c]	X	X
HIV viral load testing (if HIV positive)[d]	X	X
Laboratory Evaluations/Procedures (Local LDMS Lab)		
DBS processing and storage[e]	X	X
Plasma processing and storage[f]	X	X
DBS and plasma shipping to HPTN LC laboratories, when requested[g]	X	X

[a] Separate blood specimens will be collected for testing at the commercial laboratory and for plasma storage.

[b] Blood specimens for testing at the commercial laboratory should be labeled and shipped to the commercial laboratory following procedures in the SSP Manual.

[c] HIV testing will be performed at a commercial laboratory designated by the HPTN LC. The HPTN LC will determine/approve the algorithm used for HIV testing. Results from this testing will be submitted to the SDMC by study staff; these results will not be returned to study participants by the HPTN LC.

[d] HIV viral load testing will be performed at the commercial laboratory for participants with HIV infection. These results will be submitted to the SDMC by study staff; these results will not be returned to study participants.

[e] DBS samples must be delivered to the local LDMS laboratory within 24 hours of collection (see SSP Manual). The laboratory may also receive DBS samples within 48 hours of collection shipped from other HPTN 096 communities that do not have a local LDMS laboratory (see SSP Manual). The laboratory will label the DBS samples in LDMS and store the DBS samples following procedures in the SSP Manual. DBS samples will be used for specialized laboratory assessments at the HPTN LC. These assessments will be performed retrospectively; results will not be returned to study sites or participants.

[f] Blood samples must be delivered to the local LDMS laboratory within 6 hours of collection. The laboratory will prepare LDMS-labeled plasma aliquots and store the aliquots following procedures in the SSP Manual. Stored plasma will be used for quality assurance testing and other exploratory assessments at the HPTN LC, see Section 10.3. These assessments will be performed retrospectively; results will not be returned to study sites or participants.

[g] The HPTN LC will provide specimen lists for DBS and sample shipping to HPTN laboratories. Instructions for specimen shipping will be provided in the SSP Manual.

APPENDIX IB: SCHEDULE OF EVALUATIONS AND PROCEDURES (No Local LDMS)

Communities that DO NOT have a local LDMS Laboratory

Procedures	Baseline (Month 0) Intervention and SOC communities	Post implementation (Year 3) Intervention and SOC communities
Administrative and Behavioral Evaluations/Procedures		
Informed Consent	X	X
Eligibility Assessment	X	X
PTID Assignment	X	X
Limited Contact/Locator Information	X	X
Coupon Disbursement (for RDS)	X	X
Reimbursement Provision	X	X
Social Harm Assessment	X	X
CASI Assessment (including demographics)	X	X
Provision of link to online survey	X	X
Counseling		
Offer condoms, lubricant, prevention materials	X	X
Clinical Evaluations/Procedures		
Fingerstick collection of dried blood spots (DBS)	X	X
Blood collection for HIV and viral load testing[a]	X	X
Ship blood samples to the commercial lab for testing[a]	X	X
Ship DBS samples to the designated HPTN 096 LDMS laboratory[b]	X	X
Provision of mail-in HIV test kit or voucher (if desired)	X	X
Laboratory Evaluations/Procedures (Commercial)		
HIV testing[c]	X	X
HIV viral load testing (if HIV positive)[d]	X	X

[a] Blood specimens will be collected for HIV and viral load testing at the commercial laboratory. These samples should be labeled and shipped to the commercial laboratory following procedures in the SSP Manual.

[b] For communities that do not have a local LDMS laboratory, DBS samples will be shipped to a designated HPTN 096 LDMS laboratory (see SSP Manual). DBS samples must be received at the LDMS laboratory within 48 hours of collection.

[c] HIV testing will be performed at a commercial laboratory designated by the HPTN LC. The HPTN LC will determine/approve the algorithm used for HIV testing. Results from this testing will be submitted to the SDMC by study staff; these results will not be returned to study participants by the HPTN LC.

[d] HIV viral load testing will be performed at the commercial laboratory for participants with HIV infection. Results from this testing will be submitted to the SDMC by study staff; these results will not be returned to study participants.

APPENDIX II: HPTN 096 PILOT SCHEMA, PROTOCOL, AND INFORMED CONSENT FORMS

APPENDIX IIA: HPTN 096 PILOT SCHEMA

Pilot Purpose: The purpose of the HPTN 096 pilot is to identify challenges and refine all components of the integrated strategy, as well as the cross-sectional assessment, prior to full study implementation.

Pilot Design: The pilot is a scaled-down version of the protocol that will be implemented in a subset (two pairs) of the selected matched-pair study communities (i.e., two intervention and two control communities). During the pilot, all four components of the integrated strategy will be conducted in the two pilot intervention communities. The cross-sectional assessment will be implemented in all four pilot communities. To the extent possible, study components will be implemented with fidelity to the planned design and activities as described for full implementation in the main study protocol, except that they will be conducted in fewer communities. In some cases, activities may be condensed or prioritized to conform to the pilot period timeframe. During the pilot, activities to prepare for full study implementation after the pilot will concurrently be conducted in all remaining communities (both intervention and control). The pilot will represent the start of study implementation for the four pilot communities.

Pilot Integrated Strategy Components: The four pilot study components are described below:

Health Equity: During the pilot, one community coalition will be established in each of the two pilot intervention communities. Local community-based organizations will be engaged to serve as organizers, coordinators, and implementers of the coalitions in their communities. After coalitions are established, prioritization will be given to implementing a limited set of HPTN 096 community coalition activities within the remainder of the pilot period, as time allows. These activities include study-specific training, initial resource mapping, one equity forum and activities that synergize with the other intervention components. In addition, the web-based resource guide platform for coalitions to use to house a curated list of service providers will be developed.

Social Media Influencers (SMI): During the pilot, at least two and up to four SMI will be identified in each of the four pilot communities (2 intervention and 2 control), for up to a total of 16 SMI. In the intervention communities only, SMI will provide messaging on HIV-related topics as described in the main study protocol. In both intervention and control communities, SMI will promote cross-sectional assessment activities as described in the main study protocol.

Intersectional Stigma Reduction: During the pilot, two healthcare facilities (HCFs) in each of the pilot intervention communities will be selected to participate in the pilot (four HCFs total). In these four pilot HCFs, staff will complete the primary elements of the intervention as described in the main study protocol, as follows: >75% of relevant staff (e.g., the clinical staff who directly provide HIV treatment or prevention services, and the non-clinical staff who support or provide administrative leadership to them) at each facility will complete the Foundation training, and a subset of staff at each facility will complete an abridged Extension for Community Healthcare Outcomes (ECHO)

curriculum, participate in Quality Improvement (QI) activities, and participate in simulated client-instructor experiences.

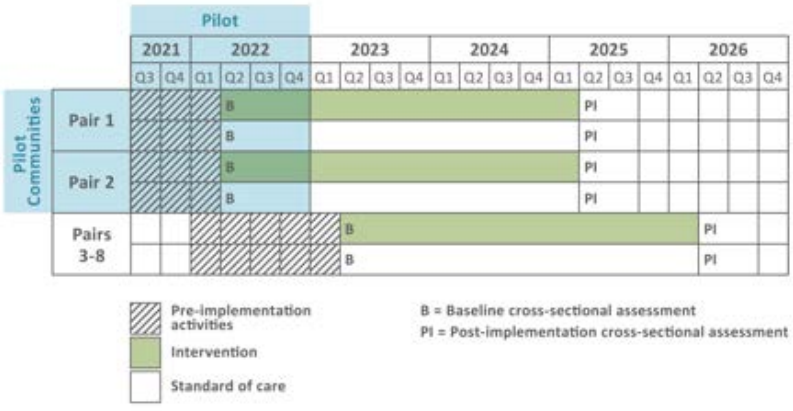
Peer Support: During the pilot, four peer support workers will be hired and trained to provide practical and emotional support to Black MSM in each of the two pilot intervention communities. The training and oversight of the peer support workers will be conducted as described in the main study protocol. A web-based platform will be established to support the program.

Pilot Baseline Cross-Sectional Assessment: The pilot cross-sectional assessment will be conducted in the two pilot intervention communities and the two control communities with which they are paired. The assessment will be conducted as described in the main study protocol, including a sample size of 100 Black MSM in each of the four communities for a total of 400 individuals. The pilot cross-sectional assessment will serve as the baseline assessment in these four communities.

Community Engagement: Community engagement will be directed at three levels: 1) general awareness of the study, 2) component-specific engagement, and 3) indirect recruitment for the cross-sectional assessment. Each level of engagement will specifically target appropriate audiences using various methods of engagement. During the pilot, a stakeholder mapping exercise will be completed to determine appropriate stakeholders at each level of engagement, and how much engagement, communication or consideration is needed. This will allow better prioritization of stakeholders and for focused efforts at each individual level of engagement in the most impactful way.

Pilot Communities: A total of 16 study communities (making up 8 matched pairs) will participate in full protocol implementation; however, the pilot will include only four of these communities – two intervention communities and the two control communities with which they are paired. These two pairs will be chosen after all study communities are randomized such that the integrated strategy and cross-sectional assessment is conducted in a variety of different environments during the pilot.

Pilot Duration: The pilot will be conducted in two parts, preparation (pre-implementation) and implementation, with preparation lasting approximately 8 months in pilot communities and implementation lasting up to 9 months in pilot communities. Preparation will continue throughout the pilot period in the non-pilot communities. The figure below depicts the pilot duration in the context of the overall study timeline.



Summary of Pilot Outcome Measures: The outcome measures for the pilot are designed to monitor the success of establishing and implementing the four components of the intervention and community engagement in two intervention communities, and the cross-sectional assessment in the two intervention communities and the two control communities with which they are paired. The primary, secondary and exploratory objectives described for the full study will not be used as outcome measures for the pilot. However, many of the process measures described in the main study protocol will be used to assess the success of the pilot and are reiterated within the description of the pilot. In addition, during the pilot period, activities to prepare for full study implementation in non-pilot communities will also be used as a measure of success of the pilot; specifically, gaining agreement of laboratories in all 16 communities, and HCFs in all 8 intervention communities, will be key measures of success.

APPENDIX IIB: HPTN 096 PILOT PROTOCOL

1.0 PURPOSE OF THE PILOT

The overall purpose of the HPTN 096 pilot is to identify challenges and refine all components of the integrated intervention strategy and the cross-sectional assessment before full study implementation. In line with the precedence set with other NIH-sponsored trials, this pilot will be an opportunity to potentially refine the protocol, improve operational feasibility, enhance community participation, and increase stakeholder engagement before implementing the integrated strategy in all study communities at full capacity. In addition, the pilot will be a chance to identify and address any unforeseen impediments to reaching Black MSM with this integrated approach and explore how the intervention components may work synergistically or antagonistically with one another. Most critically, the pilot will allow the study team to identify and find solutions for anticipated (and unanticipated) challenges so that the integrated strategy can be implemented with fidelity and synergy within complex environments during full implementation.

It is anticipated that the pilot will address potential challenges such as the potential for community coverage, how the intervention components will interact with one another, and how the impact of the intervention components will be measured. In addition, a vital part of the pilot will be establishing and maintaining sustainable community engagement -- especially the support and engagement of Black MSM -- as well as maintaining close collaboration between the study team, CDC, HRSA, and other entities funding and implementing the Ending the HIV Epidemic (EHE) initiative. Unlike the main study protocol, the pilot is not designed to demonstrate changes in the study's primary outcomes (e.g., PrEP uptake, viral suppression) due to the pilot's short time frame and small scale. Lessons learned during the pilot will serve to improve the final study design and increase the chances of success when the study is fully implemented in all communities.

2.0 OVERVIEW OF THE PILOT DESIGN

The approach for the pilot will involve implementation of a scaled-down version of the protocol in a subset (two pairs) of the selected matched-pair study communities (i.e., two intervention and two standard of care communities). During the pilot, all four components of the integrated strategy will be conducted in the two pilot intervention communities. The cross-sectional assessment will be implemented in all four communities. The pilot will represent the start of study implementation for the four pilot communities. In this way, the pilot will serve as a staggered start of the full study (see Pilot Appendix Figure 1). To adhere to the community-randomized design of the main study protocol, it is critical that implementation of the study begin and end in each pair at the same time, but the start of each individual pair may vary. Statistical considerations for the pilot, including a description of how the pilot activities and data from pilot communities will be factored into the overall study analyses, is included in Pilot Appendix Section 11.0.

To the extent possible, study components will be implemented with fidelity to the planned design and activities as described for full implementation in the main study protocol, except that they will be conducted in fewer communities. In some cases, activities may be condensed or

prioritized to ensure that they are able to be tested during the pilot period timeframe. A natural period of implementation scale-up is to be expected in any implementation context, so while the pilot may involve smaller scale implementation than described in the main study protocol (e.g., fewer peer support workers, fewer health care facilities) a similar trajectory is expected to occur naturally in non-pilot communities when implementation of the full study begins. However, for the full study, initial implementation is generally expected to start at a larger scale before ramping up quickly to full implementation. Where prioritization of activities is required, activities selected for implementation in the pilot are those that are anticipated to be the most challenging or consequential for the success of the study component and thus require testing in the pilot. Pilot Appendix Sections 4.0, 5.0, 6.0 and 7.0 summarize the pilot activities for each component of the integrated strategy and identify where planned pilot activities may differ from those described in the main study protocol. Implementation of the integrated strategy in the pilot intervention communities is anticipated to continue past the pilot period for the full duration of study implementation, eventually reaching full scale implementation of each component in the pilot communities after the pilot period. Transition from pilot to full study implementation is described in Pilot Appendix Section 12.0.

2.1 Assessment of Pilot Outcome Measures

Pilot outcome measures for each component of the integrated strategy and the cross-sectional assessment, as well as community engagement efforts, are described in each respective section below. Pilot outcome measures have been selected based on their ability to serve as indicators of operational and feasibility success and are not intended to demonstrate changes in the main study outcome measures (i.e., viral suppression or PrEP use). In general, assessment of pilot outcomes will be continuous to allow for real-time adjustments to implementation. Indicators of success span the entire pilot time period and will largely be assessed in the four pilot communities (as applicable); however, some indicators will also assess the success of activities in preparation for full implementation in non-pilot communities. Specifically, gaining agreement of laboratories in all 16 communities, and HCFs in all 8 intervention communities, will be key measures of success.

Indicators will be evaluated and reported on an indicator-specific basis; those that are met quickly will be reported formally and in writing to the study sponsor as they are determined, rather than reporting on all indicators at the end of the pilot period. This approach will allow for adequate time to incorporate all lessons learned into the study protocol and into study procedures in advance of implementing the full study and will provide as much time as possible for review by the study sponsor.

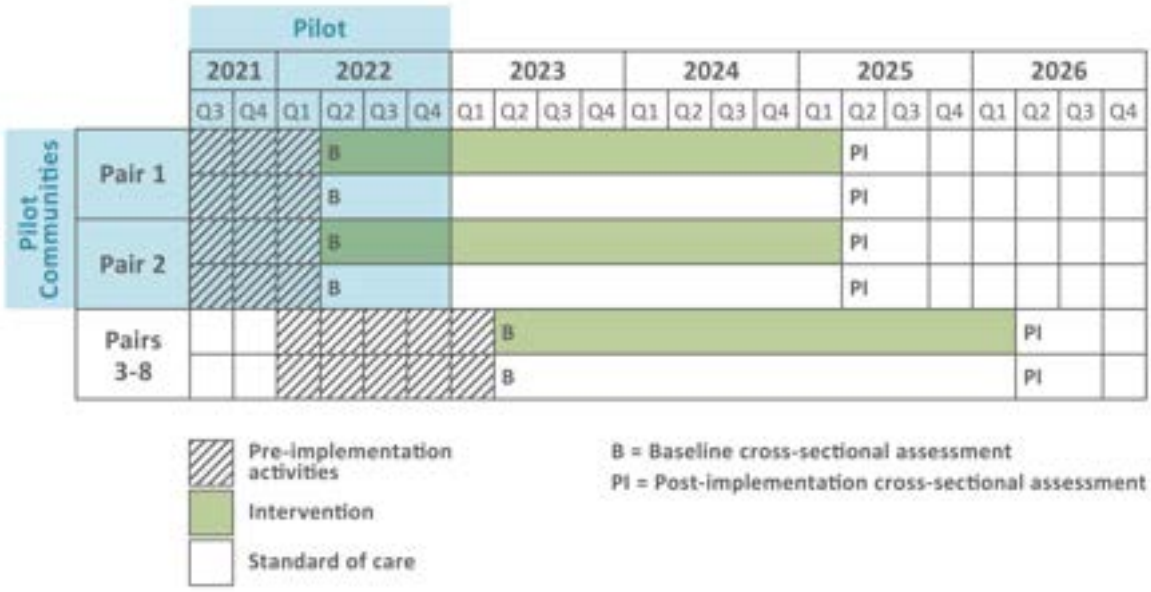
2.2 Timeline for Pilot

The timeline for the pilot is from August 2021 through December 2022. This timeline is inclusive of pre-implementation activities, which will occur in pilot communities between September 2021 and April 2022, as well as assessment of pilot outcome measures. Additional time will be needed to complete retrospective testing of specimens collected in the pilot study (HPTN LC testing). Note that completion of this testing and analysis of test results are not included in the pilot study outcome measures. The start of implementation of the baseline cross-sectional assessment will mark the starting point of the study implementation period in the four

pilot communities, and is anticipated for April 2022, though this timeline may shift depending on readiness of the pilot communities. For the pilot, implementation of the integrated strategy will begin in parallel with the start of the baseline cross-sectional assessment, as it is not expected that implementation of the integrated strategy in intervention communities will produce immediate changes in study outcome measures detectable at the population level that may interfere with a baseline assessment.

Pilot Appendix Figure 1 summarizes the timeline for the pilot and how the pilot is integrated into the full study timeline.

Pilot Appendix Figure 1. Pilot and Full Study Implementation Timeline



2.3 Activities in Non-Pilot Communities during Pilot Implementation

If the pilot demonstrates success, full implementation of the main study protocol in all matched pairs is expected to begin shortly after completion of the pilot phase, after a short transition period for final assessment of pilot outcomes and incorporation of lessons learned into the main study protocol and study procedures (see Pilot Appendix Section 12.0). In anticipation of full implementation, pre-implementation activities will concurrently be conducted in all non-pilot communities (both intervention and control) during the pilot period. No study implementation activities will occur in non-pilot communities during the pilot period; rather, pre-implementation activities will focus on building a solid foundation and infrastructure on which to begin study implementation once the full study begins, such as identifying local implementing partners and building awareness. Pre-implementation activities planned for the pilot period that are related to each component of the integrated strategy and the cross-sectional assessment are specified in the respective sections below.

3.0 PILOT STUDY COMMUNITIES

Two study community pairs, which will include two intervention and two control communities, will be chosen for the pilot. The overarching principle used to choose these two pairs is to conduct the pilot in a wide variety of settings so that the lessons learned from the pilot will be generalizable to all 16 study communities. The pilot communities will be chosen primarily using the following parameters:

- Community size, using the urban influencer code
    - Both small and large communities will be included as pilot communities
- BTAN establishment*
    - Communities with a local or statewide BTAN chapter or affiliate and one without an established BTAN will be included as pilot communities

      *Note: This criterion was used to choose pilot communities based on the original intention to partner with Black AIDS Institute using the BTAN model for the Health Equity component. As described in Pilot Appendix 4.0, the Black AIDS Institute will no longer serve as implementing partner for the Health Equity component. However, this decision was made after this criterion was used in the pilot selection process.
- LDMS laboratory capacity
    - Communities with and without established LDMS laboratories will be included as pilot communities

In addition, the presence of Black leadership and/or organizations by and for Black MSM will be taken into consideration, as this may facilitate pilot implementation in a short time frame.

4.0 HEALTH EQUITY PILOT COMPONENT

4.1 Pilot Component Description

The health equity component as described in the protocol involves establishment of community coalitions to shape community social norms within the local service sectors to be supportive of wide-scale adoption of HIV testing, PrEP use and treatment engagement to reduce HIV inequities among Black MSM. This basic concept and design will remain the same during the pilot; however, community coalitions will no longer be based on the Black Treatment Advocates Networks (BTAN) model administered by the Black AIDS Institute. Instead, community coalitions will be established through local community-based organizations (CBOs), with CBOs serving as the primary implementing partner in each community to coordinate and administer the coalitions, and study-specific coalition activities guided by Pilot Appendix Table 1 below. Additionally, during the pilot period, coalitions will only be fully established in the two pilot intervention communities, with the primary goal being to have the two coalitions in place by the end of the pilot period.

Formative work by local CBOs to establish the coalitions in their communities will occur generally as described in the protocol. A community engagement strategy will be developed for

CBOs to use as a resource to guide this work. This strategy will be tested and refined during the pilot period with the two pilot intervention communities and will be used during the preparatory period in non-pilot communities.

The full set of activities that an HPTN 096 community coalition would be expected to engage in during the course of the HPTN 096 study are described in Pilot Appendix Table 1. As described in the main protocol, HPTN 096 community coalitions will facilitate the effects of the other HPTN 096 components by promoting norms within the local service sectors (e.g., social, legal, economic) that support the strategic prioritization of access to resources and services for Black MSM that can minimize barriers to HIV testing, PrEP use and viral suppression; and they will amplify the effect of the other HPTN 096 components through the integration and promotion of HPTN 096 into its community mobilization activities, thereby increasing Black MSM's receptivity to the use of HIV testing, PrEP and other HIV prevention services, ART, and virtual peer support.

Pilot Appendix Table 1. HPTN 096 Community Coalition Program Model

HPTN 096 Community Coalition Model	
Facilitation	**Amplification**

▪ Convene monthly coalition meetings to plan HPTN 096-related activities
▪ Participate in CRISP (intersectional stigma reduction) foundation training.
▪ Completion of study-specific coalition training, including structural competency, civil engagement policy and advocacy, and HIV scientific literacy.
▪ Participate in at least one annual refresher training on HIV prevention, scientific literacy policy, advocacy, civil engagement, and structural competency.
▪ Initial rapid mapping exercise to identify local resources and services that may help alleviate structural impediments to HIV testing, PrEP and/or treatment for Black MSM.
▪ Annual "booster" mapping activity to assess changes in landscape of local resources and services.
▪ Convene multi-sector (e.g., education, housing, legal services, drug treatment and addiction, human services) service provider equity forum(s) (with follow-up events at most annually thereafter) to:
  ▪ Raise awareness of EHE goals
  ▪ Raise awareness of HPTN 096
  ▪ Illustrate the connection between their services and EHE goals
  ▪ Encourage cooperation to leverage their services to reducing structural barriers to HIV prevention for Black MSM
  ▪ Create and maintain curated roster of service organizations for Black MSM
	▪ Localize and incorporate HPTN 096 messages through coalition outreach, other community outreach and communication, and educational channels, including raising awareness of other HPTN 096 study components.
	▪ Collaborate on HCFs action planning to support CRISP intervention.
	▪ Annual Community Coalition Best Practices meeting to share best practices re: HCF collaborations, resource mapping exercise, and any other amplification strategies.
	▪ At least one annual advocacy event focused on intersectional stigma reduction with Black MSM
	▪ At least one annual science event focused on current advances in HIV prevention and treatment (e.g., PrEP options, ART options, HIV/STI self-testing options).

Given the anticipated time required to establish coalitions during the pilot period and the short duration of the pilot, the pilot coalitions will not be expected to complete all HPTN 096 community coalition activities as described in Pilot Appendix Table 1 within the pilot period. Once coalitions are established, activities will be prioritized for completion during the pilot period as follows:

- Completion of study-specific coalition training, including structural competency training
- Initial rapid mapping exercise to identify local resources and services

- Completion of monthly coalition meetings
- Incorporation of HPTN 096 messages through community outreach, including raising awareness of other HPTN 096 study components
- Convening of multi-sector service provider equity forum

Additionally, the web-based platform that will host the curated roster of services identified through the rapid mapping and equity forum activities will be designed, developed, tested and built during the pilot period. This platform will be developed centrally for use by the local community coalitions. It is not expected that coalitions will complete the curated list of service providers with which to populate the web-based platform within the pilot period, though the pilot coalitions may begin the process of identifying local service providers and populating the platform during the pilot period for the purposes of functionality testing of the platform.

4.2 Preparatory Activities in Non-Pilot Communities

While community coalitions will not formally be established in any non-pilot intervention communities during the pilot period, formative work will take place in these communities during the pilot period to identify and establish potential CBO partnerships for coalition building once full implementation commences. In each non-pilot intervention community, this formative work will include implementation of the community engagement strategy, including community outreach and partnership building activities. During the pilot period, in non-pilot intervention communities, the goal will be to identify local CBO partners who can establish the foundation upon which coalitions can be built during the full implementation period. This includes putting in a place a Memorandum of Agreement with at least one CBO in each non-pilot intervention community by the end of the pilot period which will set the terms for community mobilization and coalition building activities once full implementation is initiated.

4.3 Pilot Outcome Measures

A sub-set of health equity component process measures described in the protocol, generalized to community coalitions rather than BTAN chapters, will be used to assess outcomes of the pilot. Specific pilot measures that will be assessed in pilot intervention communities include:

- Agreement in place with local CBO to serve as implementing partner in each pilot intervention community
- CBO establishment of community coalition in each pilot intervention community and length of time required for establishment
- Number/types of engagement activities used by CBOs in the formation of the community coalitions
- Number of meetings and attendance at each meeting for each pilot intervention community coalition
- Composition of each pilot intervention community coalition (number of people, number and types of organizations represented, roles/positions of members, sexual orientation and gender identity of members)

- Metrics of engagement of pilot community coalition members (e.g., number and percentage of members who participate in each type of coalition activity)
- Number, type and timing of HPTN 096 community coalition activities completed by each intervention coalition within the pilot period

Additionally, success of engagement with non-pilot intervention communities for the purposes of laying the foundation for establishing community coalitions in those communities in the full implementation period will be assessed at the end of the pilot period. Metrics for success include:

- Memoranda of Agreement signed by local CBO implementing partners in each non-pilot intervention community declaring intention to establish community coalitions once the full implementation period begins.

4.4 Human Subjects Considerations

There are no differences with regard to human subjects considerations between the pilot and what is described in the main study protocol for the health equity component.

5.0 SMI PILOT COMPONENT

5.1 Pilot Component Description

During the pilot, the SMI component is expected to be conducted as described in the main study protocol, with the exception being that it will not be carried out in all study communities. At least 2 and up to four SMI, which is the upper limit of the range described in the main study protocol, will be identified in each of the four pilot communities (2 intervention and 2 control), for up to a total of 16 SMI. In the pilot intervention communities, SMI will provide messaging on HIV-related topics, as well as the promotion of other study components, as described in the main study protocol. In both intervention and control communities, SMI will promote cross-sectional assessment activities as described in the main study protocol.

As described in the main protocol, the protocol team will rely on the Community Strategy Group (CSG), Community Advisory Group (CAG) and a social media firm to identify and vet SMI who have a following in the local Black MSM community. The selected SMI will be trained, expected to post on a regular basis based on given prompts, and monitored, as described in the main protocol. As part of the pilot, input on the training, prompts, posting and messaging will be sought from the SMI chosen for the study, and potentially, from other SMI who are familiar with the study population, HIV-related messaging and/or study promotion. The pilot will also serve as an opportunity to determine what type of messages (both content and media), post frequency, and, potentially, social media platforms result in the highest engagement.

In addition, the study team will use an advertising-based methodology to disseminate information via social media. Black MSM, or other individuals who are recognized by or are known to have influence in the Black gay community, will be approached to create content; however, existing content will also be considered, such as HIV-related content made by public health institutions, foundations, public-private partnerships, or other organizations that support Black MSM. While existing content may be readily available and professionally produced, new content will augment resources that may resonate with Black MSM because it is non-

establishment, relatable, based on lived experience, and unique. This combination of new and existing content will allow the team to create a library of advertisements so that messaging remains fresh. By creating social media advertisements with both existing and newly created content, the study will leverage the broad knowledge and experience of the Black gay community, as well as existing resources, to reach Black MSM within study specific communities. While social media advertising has been used by others to disseminate health information with the goal of behavioral change, the innovation of this approach will be that the campaign takes place within a community where the barriers that Black MSM face with regard to HIV prevention and care are being lowered by the other three study components. These ads are intended to encourage men to seek out HIV testing, PrEP and care, and they will be doing so in an environment where these options are more accessible and welcoming.

One of the current limitations of social media advertising is that it cannot be used to target ads based on race or sexual orientation. Instead, advertisers try to reach their intended audience by choosing interests – for example specific entertainers or popular celebrities – that the social media algorithms use to distribute the content. But how social media platforms currently work, it is not possible to determine who sees the ads beyond location, age and gender. For example, an ad can be sent to men in Dallas who have expressed interest in RuPaul, Queen Sugar and Diana Ross – but social media metrics do not measure and report if Black MSM see the ad. HPTN 096 will gather data using standard website analytics tools and methods from the people who see these ads to determine if they are reaching the study population.

5.2 Pilot Outcome Measures

For activities involving social media influencers, the pilot outcome measures for the SMI component are the same as described as the process measures for this component in the main protocol, with one exception, and are reiterated below. The one exception is that in the main study protocol, "time spent on links/videos" is included, and for the pilot, this measure has been replaced with "number of views per post." The reason for this change is because some social media platforms do not consider engagement as a "view" until a certain amount of time has been spent, thus, it was felt that enumerating the number of views per post is a better measure of engagement.

Measures of penetration of the SMI activities:

- Number of SMIs in each region/community
- Metrics of social media engagement, including the following:
    - Clicks on links/videos
    - Number of views per post
    - Number/types/demographics of followers of SMIs
    - Number and types of reposts/retweets
    - Comments (stratified by social media platform and SMI components)
    - Types of content developed
- Measures of fidelity to the planned SMI activities:

- Retention rate of SMIs in each community
- Frequency of SMIs postings and activity
- Content analysis of SMIs' postings and activity as compared to content guide

For activities involving social media advertising, all ads will be monitored for reach and engagement. These data will be captured in real-time and used to adjust subsequent ads. As all ads will include a link back to the HPTN 096 webpage, the team will monitor both social media advertising and website metrics. This monitoring will include the temporal relationship between ad distribution and ad engagement. In addition, website and ad viewing data collection measures will also include short, non-invasive, anonymous, questions asked to viewers of ads and those who land on the HPTN 096 webpage (e.g., a pop-up window that asks, "Is the information on this website useful to you?") and may also collect information about race, gender and sexual orientation.

In addition to determining whether the ads are reaching the study population, the team may conduct A/B testing to compare different ads, or different distribution elements (e.g., the interests used to target the ads), to determine which approach works best. Some social media platforms (e.g., Meta, which includes Facebook and Instagram) have the capacity to distribute two ads simultaneously to two equivalent segments of the intended audience, ensuring that no one sees both ads. This allows for a head-to-head comparison of the performance of each ad. Lessons learned from this testing will be incorporated into the next iterations of ad distribution.

Process measures for social media advertising will include:

- Measures of penetration of the social media activities:
  - Number, topic, type (e.g., video, text-based, etc.) and the social media platform used for distribution of all social media advertisements deployed in each intervention community
- Metrics of social media advertising engagement, including the following:
  - Impressions (number of views) and reach (number of unique individuals viewing each ad). These metrics will be compared to the estimated number of Black MSM in each study community.
  - Clicks on embedded links
  - Number and types of other engagement (e.g., saves, likes, comments, reposts, etc.)
- Measures of engagement with and use of the HPTN 096 website
  - As all ads will include links back to the HPTN 096 website, website analytics will be used to capture engagement, which will include, but are not limited to:
    - User location
    - Page views
    - Average time on page
    - Average session duration
    - New and repeat visitors

        - Event tracking (captures actions visitors do on the page, for example going from one page to another)
    - To determine if Black MSM are seeing the ads, pop-up questions will be employed to collect additional anonymous information on those who click on the ad links and land on the HPTN 096 webpage. These questions may include, but are not limited to:
        - Yes/no feedback on utility of information provided on website
        - Questions about whether the user likes the ads/website
        - Questions to better understand who is viewing the ads, such as race, sexual orientation, and gender identity
- Measures of fidelity to the planned social media activities:
    - Creation and distribution of at least four social media advertisements each quarter (16 per year) to intervention communities

5.3 Human Subjects Considerations

In general, there are no differences with regard to human subjects considerations between the pilot and what is described in the main study protocol for the SMI component. However, the limited data that will be collected from some people who see and interact with the social media advertisements is considered to be human subjects research. As individuals will not be enrolled in the study and data will be collected anonymously, it is expected that this activity will meet the definition for exemption under 45 CFR 46.104(d)(2)(i). The questions to be answered anonymously will be submitted to and approved by the IRB prior to implementation.

5.4 Preparatory Activities in Non-Pilot Communities

During the pilot, preparation will take place so that the SMI component can be conducted in all non-pilot communities after the pilot ends. These preparatory activities will include:

- Identification and, if funding allows, procurement of the social media firm that will be used for implementation of the full study
- Identification and vetting of SMI in all non-pilot communities
- As funding allows, contracts will be put into place with the identified SMI, and, if this takes place, these SMI will undergo initial training.

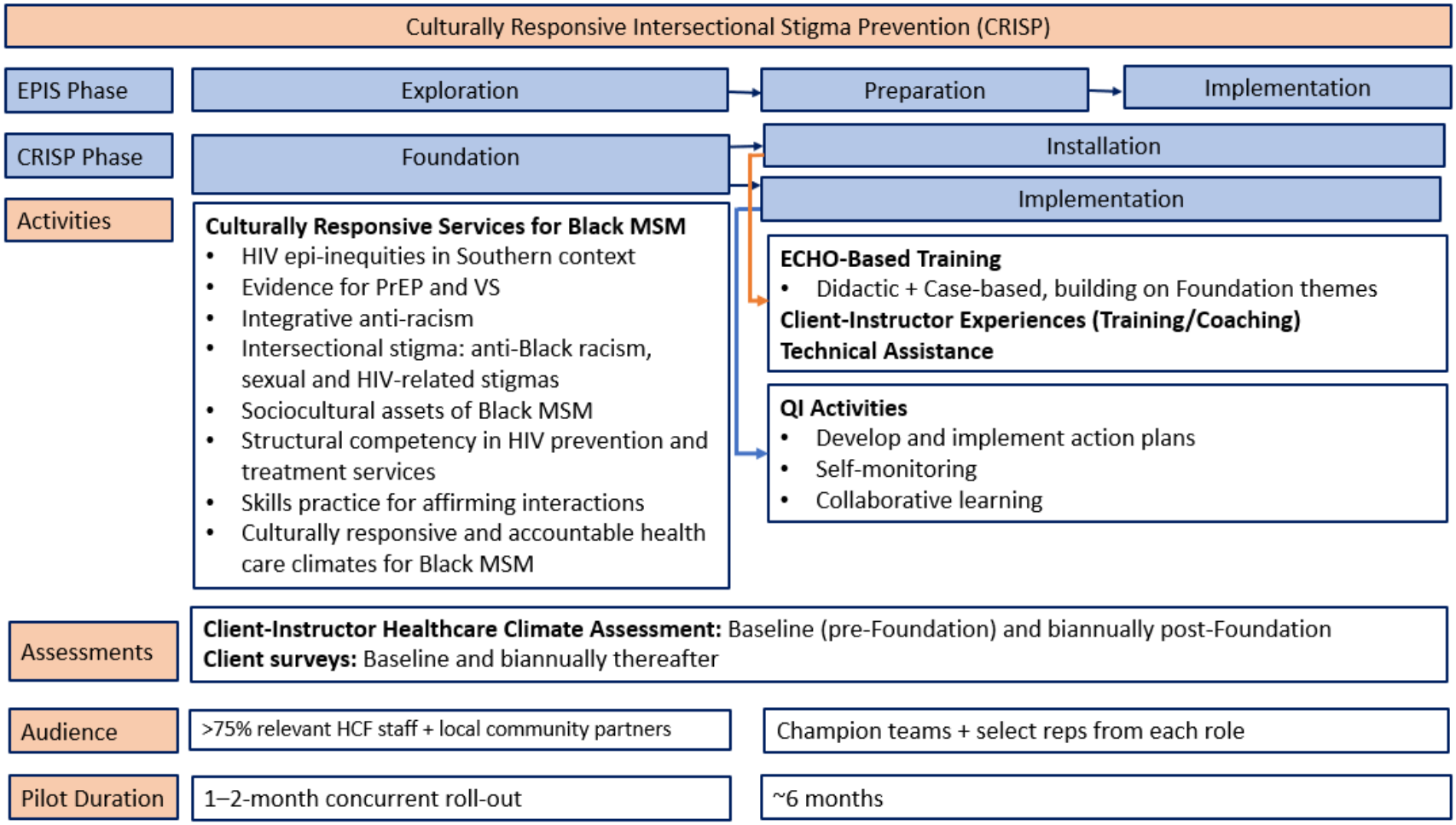
6.0 INTERSECTIONAL STIGMA REDUCTION PILOT COMPONENT

6.1 Pilot Component Description

The Culturally Responsive Intersectional Stigma Prevention (CRISP) component, as described in the main study protocol, involves three phases (Foundation, Installation, and Implementation), with certain activities associated with each phase. During the pilot, the goal will be to have an opportunity to implement key activities within each of these phases, to ensure the entire package is able to be implemented and refined. To accomplish this within the timeframe of the pilot, implementation will occur at only two health care facilities (HCFs) in each of the two pilot

intervention communities, for a total for 4 pilot HCFs. The pilot HCFs will each represent different healthcare environments and a range of size and type of facility will be targeted for inclusion (e.g., community health center, AIDS service organization, hospital, etc.). This small number of HCFs will allow for implementation of more elements of CRISP within the shorter pilot period; additionally, some activities within the Installation and Implementation phases will be implemented concurrently, rather than sequentially as described in the main study protocol. Specific activities for the pilot implementation of CRISP are described in the following sub-sections, and a summary of the CRISP implementation plan specific to the pilot period is shown in Pilot Appendix Figure 2.

Pilot Appendix Figure 2. CRISP Pilot Implementation Plan



6.1.1 Foundation Phase

This training will be as described in the main study protocol, except it may be facilitated by a central training team rather than by local teams of interventionists, in order to provide time to determine the best staffing strategy for use in the full implementation period and identify and train local interventionists. The pilot will serve as an opportunity to test the Foundation curriculum. The aim will be to complete the Foundation training with >75% of relevant staff (e.g., the clinical staff who directly provide HIV treatment or prevention services, and the non-clinical staff who support or provide administrative leadership to them) trained at the 4 pilot HCFs. The Foundation training will begin in parallel with or shortly after the start of the baseline cross-sectional assessment, and immediately after the Client-Instructor Healthcare Climate assessments and baseline client surveys have been completed at each HCF.

6.1.2 Installation Phase

The primary Installation activities of focus during the pilot will include (listed in reference to how they appear in the protocol): a) Quality Improvement (QI) pre-work, b) Extension of Community Healthcare Outcomes (ECHO) trainings, c) Client-Instructor Experiences for training purposes, d) Technical Assistance, e) HIV Cascade Self-Monitoring for QI purposes, and f) CRISP Action Plans (as part of QI activities). Other CRISP activities described in the protocol will not be prioritized during the pilot.

- QI pre-work: Preparatory work for QI activities may begin prior to implementation of the Foundation training, as part of a QI needs assessment of participating HCFs. This assessment will determine organizational capacity for quality management, QI skills and HCFs' existing ability for self-monitoring of HIV cascade data in real time, which will be necessary for QI activities. The QI pre-work will also set expectations for working within QI networks during the pilot phase, as well as expanded QI collaboratives during full implementation. Actual QI activities at HCFs will not begin until after the Foundation training has been completed.
- ECHO: Implementation of the ECHO-based training curriculum will begin during the pilot in the 4 pilot HCFs, after completion of the Foundation training. The standard ECHO curriculum, developed for full study implementation, will be used, but completion of all sessions of the curriculum within the pilot period is not expected. ECHO sessions will be implemented in approximately the same manner and frequency as described in the main study protocol and will continue throughout the pilot period and would be expected to continue into full implementation for completion of the curriculum at the 4 pilot HCFs; the number of sessions completed will be dependent on when the Foundation training concludes, and the Installation phase begins. Central ECHO faculty will be responsible for facilitating the sessions, rather than the local interventionists as described in the protocol.
- Client-Instructor (CI) Experiences: During the pilot, CI experiences will be implemented differently than described in the protocol. The revised design for the CI experiences is expected to carry forward to full implementation, pending lessons learned in the pilot and amendment of the protocol. The new purpose of CI experiences is twofold: 1) as a CRISP

training/coaching activity, to assess and coach providers on skills that were taught in the Foundation training, and 2) as a measure of the general healthcare climate of the facility, to assess changes in care quality and care responsiveness to Black MSM over time. The training/coaching aspect of the CI experiences are described here as CRISP Installation phase activities; the healthcare climate assessment aspect of CI experiences is described below in sub-section 6.1.4 on assessments. CI experiences will be conducted at baseline (pre-Foundation training) and biannually thereafter; however, baseline CI experiences will not be used as a training/coaching tool as individual providers will not be assessed at baseline, though feedback from Cis may be used to inform the Foundation training content and Cis may also be invited to attend the trainings. A target of four CI experiences will be completed at each time point for each facility. The training/coaching aspect of the CI experiences will be implemented as described in the protocol, except that the ratings and qualitative feedback from CI experiences will only be used as a training tool for the individual provider and will not be collected, either individually or in aggregate, as study data. Ratings and qualitative feedback will be used by the CI to coach the provider immediately after the experience, and the written rating and feedback will then be provided directly to the provider after the experience and not retained by the CI or provided to the study team.

- Technical Assistance: Technical assistance (TA) may be requested by HCF and will be provided by the central CRISP study team during the pilot period. The mechanism for requesting and tracking TA may be different than described in the protocol and will be described in supportive operational documents. One operational goal of the pilot will be to develop and test the mechanism for request, provision, and tracking of TA.
- HIV Cascade Self-Monitoring: Self-monitoring of HIV cascade data, disaggregated by race, age, and sexual orientation and gender identity, will be conducted by HCFs during the pilot period as described in the main study protocol; the focus of the self-monitoring will be to support QI activities. Self-monitoring capabilities of each HCF will be assessed during the QI pre-work process for HCFs, prior to implementation of QI activities, and will inform the QI training and technical assistance that may be provided to each HCF. HIV cascade data will serve as QI indicators and will be defined as part of a study-specific QI operational plan that will be used to guide QI implementation across the facilities. In order for HCFs to assess whether their QI efforts are making a difference, HCFs will monitor QI indicator(s) relevant to the HIV cascade that they are aiming to improve. An operational goal of the pilot will be to develop and test the data collection tool(s) used by HCF in collecting QI indicator data, and to assess HCF capabilities for real-time self-monitoring of disaggregated HIV cascade clinic data during pilot implementation. Data will be reported to the central QI facilitator for QI activity purposes and will not be used as study data.
- CRISP Action Plans: CRISP action plans will be conceptualized differently for the pilot than described in the main study protocol. Action planning will instead occur as part of QI activities; specific expectations for action plans and how they will be used in QI will be described in the study-specific QI operational plan.

6.1.3 Implementation Phase

The Implementation Phase of CRISP will focus on testing key elements of QI collaboratives. While the small number of pilot HCFs will not allow for full QI collaboratives, peer exchanges will be facilitated between the pilot HCFs, and aspects of the study-specific QI operational plan will be tested within these exchanges in preparation for the establishment of QI collaboratives during full implementation. Detailed QI activities will be specified in the study-specific QI operational plan, but will emphasize implementation of improvement interventions (e.g., plan-do-study-act cycles). In addition to a HCF's self-monitoring of its population-disaggregated HIV cascade clinic-level data described in the Installation section, findings from CRISP assessments (i.e., CI assessments of the healthcare climate and client surveys) may be used for QI purposes, and QI activities may include collection of additional clinic-specific information related to intersectional stigma, for use in targeting QI interventions.

During the pilot, the Implementation phase (i.e., QI activities) will run concurrently with the Installation phase, rather than sequentially, with all activities beginning after completion of the Foundation training. QI peer exchanges during the pilot period will be facilitated by a central QI coordinator with expertise in QI methods.

6.1.4 Assessments

Assessments to be implemented during the pilot period will differ in key ways from the main study protocol description of these activities. Importantly, HCF workers will not be surveyed on measures related to intersectional stigma and implicit bias, as described in the protocol. Instead, only two types of assessments will be conducted, both of which will be used as measures of the secondary objective on care quality and care responsiveness to Black MSM needs at HCFs participating in CRISP. These assessments include 1) CI assessments of the general healthcare climate of each HCF, and 2) client surveys.

- Client surveys: Client surveys will be implemented to assess the secondary objective of measures of care quality, and care responsiveness to Black MSM needs at HCFs participating in CRISP. Administration of these surveys will be as described in the main study protocol, except email addresses will be collected in order to incentivize survey completion with gift cards (see pilot appendix Section 6.4 for further detail), and the target audience will be broader than just Black MSM clients and will include all clients at the HCF during the sampling time. Expanding the survey sample will allow for comparison of quality of care and experienced intersectional stigma across demographic groups and will facilitate feasibility. Client surveys will begin at baseline (prior to the Foundation training) and continue approximately biannually (one additional timepoint during the pilot period). Efforts will be made to ensure representative sample of Black MSM are included in the overall clinic sample, and to characterize the proportionality of the sample to the overall patient population at the clinic.

- Client-Instructor Assessment of Healthcare Climate: As described in the Installation Phase in Pilot Appendix Section 6.1.2, CI experiences will take place at each HCF during the pilot period, at baseline (pre-Foundation) and biannually thereafter (at two timepoints after the Foundation training). At each timepoint, a target of four experiences will be

completed at each HCF. During a CI experience, the CI will undergo a full simulated visit to the HCF for either HIV care or prevention services and will interact with multiple healthcare workers and HCF staff. For each experience, the CI will complete a Healthcare Climate Questionnaire (HCCQ) to assess the clinic environment and general interactions with the staff and healthcare team on measures related to care quality and responsiveness to the needs of a Black MSM client. Individual providers and staff members will not be assessed, and no information or data will be collected on individuals working at the clinic; individual provider ratings and qualitative feedback produced for the coaching/training aspect of the experience will not be captured as study data or used as an intervention assessment and will not be included in the HCCQ. Descriptive information about the visit (e.g., type of visit, date) will be captured for process information. Change in the healthcare climate over time will be assessed.

6.2 Preparatory Activities in Non-Pilot Communities

While CRISP implementation activities will only occur at four HCF across the two pilot intervention communities during the pilot, an important element of the pilot will be to demonstrate successful engagement and recruitment of HCFs in all intervention (including non-pilot) communities in preparation for full implementation. During the pilot, HCF recruitment and selection will be conducted in all eight intervention communities as described in the main study protocol. By the end of the pilot period, the goal will be to have selected the HCFs in all intervention communities that will participate in CRISP during full implementation, and to assess whether the set of HCFs is sufficient to meet the protocol target and study objectives. Letters of Intent will be signed with each selected HCF confirming their willingness to participate once the study enters full implementation. No CRISP activities will be implemented at selected non-pilot HCF until full implementation begins.

6.3 Pilot Outcome Measures

A subset of CRISP process measures described in the main study protocol, tailored to focus on assessing implementation success, will be used to assess outcomes of the pilot. An additional measure to assess ability to recruit HCF in all intervention communities will also be included.

Specific pilot outcome measures are as follows:

- Number and types of participating pilot HCF
- Numbers and roles of Champions identified at each pilot HCF
- Number, types and proportion of staff who complete CRISP Foundation training
- Time to completion of Foundation training at each pilot HCF
- Number and roles of staff participating in ECHO sessions
- Number of ECHO sessions completed by HCF staff
- Number of TA requests per pilot HCF

- Number and type (prevention or care) of CI experiences completed at each pilot HCF and number of staff participating in training/coaching
- Description of QI peer exchange established during pilot, number of HCFs and staff participating, and metrics of HCF engagement with QI peer exchanges
- Ability of facilities to collect and report HIV cascade self-monitoring QI indicators
- Number and type of improvement interventions implemented at each HCF as part of QI activities
- Number of Letters of Intent signed with HCFs in all intervention communities by the end of the pilot period, and types of HCF agreeing to participate

6.4 Human Subjects Considerations

The following clarifications are made to the human subjects considerations section of the intersectional stigma reduction component for the pilot in comparison to what is described in the main study protocol:

1. The health care worker survey assessment has been removed as a data collection activity and is no longer applicable.
2. Slight changes are made to considerations related to client surveys. The client sample will be expanded beyond just Black MSM clients to a representative sample of all clients at the facility. Additionally, the main study protocol states that clients will complete an anonymous survey which is considered human subjects research expected to be exempt under 45 CFR 46.104(d)(2)(i). For the pilot, completed surveys will be incentivized with a gift card that must be provided via email. For fraud prevention and data quality reasons, to ensure that survey participants cannot complete the survey and claim a gift card multiple times or distribute the survey to others, unique codes will be generated by the data management center and distributed to participating HCFs. HCFs will be asked to distribute a unique code to all clients who visit their clinic during the sampling time frame. Clients must enter a unique code into the survey to begin the survey, and unique codes may only be used once. To receive a gift card at the end of the survey, clients must opt in to providing an email address and upon doing so, will be redirected to a separate survey to collect their email address. This gift card survey will collect only the unique code and the email address for gift card distribution. The email addresses from the gift card survey will be collected and stored in an entirely different database than the main survey responses. However, because the email addresses will have the unique codes stored with them, email addresses could theoretically be linkable to survey responses. As such, this activity is not considered anonymous and no longer meets exemption under 45 CFR 46.104(d)(2)(i); however, it is expected that this activity will instead meet the definition for exempt under 45 CFR 46.104(d)(2)(iii).

   To meet 45 CFR 46.104(d)(2)(iii), the HPTN sIRB must determine that there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data. Measures will be taken to protect the privacy and confidentiality of the email addresses and survey responses. The main survey data will be collected in a Part 11 compliant database. Unique codes are used only to ensure that a survey is completed only

once by any given respondent and will not be used as participant identifiers or included in survey data reports; HCFs will not assign unique codes to specific individuals or link them to client names. Email addresses will not be stored with main survey responses. The email addresses will be housed in a different database, using a separate survey platform, than the main survey, and only the unique code and email address will be stored. Email addresses will only be used for the purposes of distributing gift cards and will not be shared with participating HCFs or linked to main survey responses. Survey respondents will be informed within the survey text that their email address will be collected for gift card distribution only, and must specifically agree to provide their email address for this purpose.

3. No changes are made to the process measures considerations.
4. CI experience ratings will be provided to the HCF workers and will not be collected as study data. Instead, client-instructors will complete a general assessment of the HCF climate and their visit experience using a standardized questionnaire. This activity is not considered human subjects research as no information about a living individual will be collected in the questionnaire, and all information recorded about living individuals as part of the training/coaching element of the CI experience will be provided directly to the HCF worker and not retained as study data.

7.0 PEER SUPPORT PILOT COMPONENT

7.1 Pilot Component Description

During the pilot, the following elements of the peer support component will be conducted as described in the main study protocol: peer support worker training, supervision, and compensation. Promotion of the peer support component by the other integrated strategy components and criteria for client/peer support worker matching will also be done in accordance with the main study protocol. The type and format of coaching and support provided to the client by the peer support workers will be conducted as described in the main study protocol. All communications between the client and peer support worker will be private and confidential in accordance with the main study protocol. Peer support workers will be trained to implement confidentiality and safeguarding protections and every effort will be made to protect the client's privacy as stated in the main study protocol. The primary shift from the main study protocol relates to how communication between the peer support workers and clients will be facilitated. Peer support workers will have access to a web-based platform; however, communications (voice, calls, and text messaging features) will not be feasible as built-in features, but available through a third-party application (for example, Zoom). A single virtual platform that houses all technical aspects of the peer support component (like a mobile app) will not be developed. In addition, a web-based portal will be established, will be managed centrally and will be designed to house appropriate resources for the peer support workers and clients. This portal will also link to the data collection system for acceptability and process measures.

As stated in the main study protocol, access to the program may be withdrawn from any clients who are found to be ineligible (i.e., do not meet the inclusion/exclusion criteria) or who violate any rules determined for participation. In addition, peer support workers will be trained to share information about organizations that provide HIV care, HIV prevention, PrEP and other services

available in the intervention communities. The main study protocol describes relying on curated resource lists developed by community coalitions in each intervention community as part of the Health Equity component as a source of information for peers to use; however, generation of this information is not expected to be completed during the pilot, as noted in section 4.1 of this appendix, thus other available resources will be used. Peer support workers may cross-share available information and the study team will collaborate with study partners (including the agencies funded by and/or implementing the EHE initiative) to generate a listing of local resources that will support the peer support workers' goal to strengthen awareness of and access to these resources. The team will also work with each pilot intervention community to better understand what peer support programs currently exist and in what ways the HPTN 096 peer support intervention can complement and align with services currently offered, as applicable.

Recruitment of peer support workers in the pilot will be limited. Up to four peer support workers will be employed in each of the two pilot intervention communities. As noted in the main study protocol, the level of effort required by each peer support worker may vary based on their individual capacity and the needs of the clients assigned to them. This will be monitored and adjusted as needed.

Program clients will be compensated for attending an initial support session in the pilot. They may also be compensated for responding to brief surveys about their experiences using the peer support program. They will not receive compensation for participating in subsequent peer support sessions.

7.2 Pilot Outcome Measures

The pilot outcome measures for the peer support component are the same as described as the process measures for this component in the main protocol, with one exception, which is reiterated below. The one exception is that in the main study protocol, the client-level measures of fidelity (satisfaction and acceptability/usefulness surveys) is assessed after a "random number of sessions." However, in the pilot, the frequency of these client level fidelity measures has been modified. The HPTN 096 SSP Manual will outline the frequency in which each measure of fidelity will be assessed. A subset of the peer support component process measures, as outlined in the main study protocol, will apply during the pilot, as follows.

The peer worker-level process measures will include:

Measures of penetration:

- Number of peer support workers recruited and trained
- Number of unique interactions between peer support workers and clients

Measures of fidelity:

- Completion of acceptability assessment (end of peer support worker participation)
- Measurement of the type of support provided during each session (e.g., topic areas)

The client-level process measures will include:

Measures of penetration:

- Number of clients who access the program, with capture of limited sociodemographic characteristics and frequency of use and type of support sought
- Measurement of where clients learned about the platform

Measures of fidelity:

- Satisfaction survey (e.g., simple single-item assessment)
- Acceptability and usefulness assessment (e.g., limited-item assessment)

7.3 Human Subjects Considerations/Confidentiality

There are no significant differences with regards to the human subjects considerations as outlined in the main study protocol for the peer support component. As described in the main study protocol, a consent form must be completed prior to gaining access to the program and support services. For the pilot we have modified the informed consent form such that participants will be requested to provide signed informed consent. This change has been made due to the change in design of the web-based portal. A template for this consent form is included in Appendix II.

As described in Section 14.3.1 and per 45 CFR 46.408(c), a waiver of parental/guardian permission will be requested for those 15 to 17 years old, as described in the main study protocol. These participants will still be required to provide assent by completing the electronic consent in the same process used for adults. All clients will have access to a copy of their informed consent form within the platform. The revised ICF, which now includes information about the study pilot, is included in Sub-Appendix I. If an IRB/EC waives the requirement of obtaining informed consent, it will not be utilized.

Limited personal and sociodemographic information (such as name, age, ethnicity, phone number, email address, etc.) may be collected from clients in order match a client with a peer support worker and may be linked to the data for acceptability and process measures. This information will be maintained confidentially and stored securely. Study data collection forms will be identified by a coded number only to maintain client confidentiality.

7.4 Preparatory Activities in Non-Pilot Communities

During implementation of the peer support component in the two pilot intervention communities, preparation will be underway in all non-pilot communities such that the peer support component can be carried out after the pilot ends. In each non-pilot intervention community, the preparatory activities will include:

- Identification and, if funding permits, onboarding and training of new peer support workers
- Identification of Black MSM-centered local resources and support services

8.0 BASELINE CROSS-SECTIONAL ASSESSMENT PILOT

8.1 Pilot Cross-Sectional Assessment Description

During the pilot, the baseline cross-sectional assessment is expected to be conducted as described in the main study protocol, except that it will only be carried out in the four pilot study communities (2 intervention and 2 control). One hundred Black MSM in each pilot community (a total of 400) will be recruited via starfish sampling, which combines venue-based (both physical and virtual venues) and respondent-driven sampling, and enrolled over the course of six months, or sooner. Local field teams will determine the venues used for sampling, which may include large events (such as gay pride) that draw from a wide geographic region, as well as smaller, local activities. All participants will be deemed eligible using the criteria outlined in the main study protocol. Biologic samples and data from two surveys will be collected from each participant, as outlined in the main study protocol. Rapid HIV testing and HIV home test kits that can be used at home will be offered to study participants during the baseline assessment but accepting them are not required for eligibility and participation. No data from the HIV rapid or home test kits will be captured in the study database.

The pilot study communities were chosen such that the baseline cross-sectional assessment will take place in communities both with and without an established local LDMS lab; this will allow the protocol team to learn how to conduct the baseline and post-intervention assessments in both types of communities.

8.2 Collection of AMIS Data During Pilot

During the pilot, the protocol team will collaborate with the PRISM Health Research team at Emory University to collect baseline data in all study communities using the American Men's Internet Survey (AMIS). AMIS is an annual cross-sectional online HIV behavioral survey of MSM in the US. The primary objective of AMIS is to monitor trends in HIV risk behavior, use of HIV testing services, and access to prevention services among gay and bisexual men in order to improve public health services for HIV prevention. The survey has been conducted annually since 2013, and it is possible to have the research team oversample in requested locations in order to collect data on men with specific demographic characteristics. The protocol team will request that oversampling be conducted in all 16 study communities such that a target of 1600 Black MSM (target of 100 per study community) complete the AMIS during the pilot. In addition, a subset of the AMIS questions will be included in the surveys conducted during the cross-sectional assessment. These data will be used to supplement the survey data collected during the baseline cross-sectional data, and to examine whether the responses are similar between the two surveys. In addition, the collection of AMIS data during the pilot will determine if it would be a useful annual measure of self-reported PrEP uptake throughout full implementation.

8.3 Pilot Outcome Measures

The pilot outcome measures for the baseline cross-sectional assessment conducted during the pilot will include the following.

Successful implementation of non-laboratory procedures, defined as:

- Identification of local partners (to serve as field teams such as community-based organizations, academic institutions, health departments, etc.) in the four pilot communities to implement the non-laboratory components of the assessment.
- Successful collection of data from both the short and long surveys in the four pilot study communities.
- Successful collection of AMIS data in all 16 study communities, with oversampling to reach a target of 100 Black MSM in each one.

Successful implementation of laboratory procedures, defined as:

- Identification and engagement of established local laboratories and commercial laboratories in the four pilot communities to implement the laboratory components of the assessment.
- Successful collection (within the required time limits), processing, labeling, transport, storage, and shipment of study samples for 100 Black MSM in each pilot community. Different procedures are required for communities that do vs. do not have a local LDMS laboratory.
- Successful reporting of results from real-time, laboratory-based testing for HIV status and viral load to the study database for 100 Black MSM in each pilot community. These results will be reported from local LDMS laboratories and commercial laboratories.

8.4 Human Subjects Considerations

As described in the main study protocol, all participants in the cross-sectional assessment will be consented prior to enrollment. Revised ICFs, which now include information about the study pilot, are included in sub-appendices (Sub-Appendix II and Sub-Appendix III).

8.5 Preparatory Activities in Non-Pilot Communities

During the pilot, preparation will take place so that the baseline cross-sectional assessment can be conducted in all non-pilot communities after the pilot ends. These preparatory activities will include:

- Identify local partners (to serve as field teams) and laboratories to conduct the cross-sectional assessments in all remaining communities (intervention and control), and if funding allows, set up contracts and/or sub-agreements with each one.
- If contracts and/or sub-agreements are put in place, supplies can be ordered, and initial training can take place for field teams and laboratories.

9.0 PREP PROVISION DURING PILOT

During the pilot, no PrEP or ART will be provided to any study communities via partnerships with pharmaceutical companies.

10.0 COMMUNITY ENGAGEMENT FOR PILOT

The HPTN 096 team recognized, through community forums and community input, the need for a multilevel, comprehensive community engagement strategy. During the pilot, community engagement will be directed at three levels: 1) general awareness of the study, 2) component-specific engagement, and 3) indirect recruitment for the cross-sectional assessment. Each level of engagement will specifically target appropriate audiences using various methods of engagement.

During the pilot, a stakeholder mapping exercise will be completed to determine appropriate stakeholders at each level of engagement, and how much engagement, communication or consideration is needed. This will allow better prioritization of stakeholders and for focused efforts at each individual level of engagement in the most impactful way.

10.1 Levels of Engagement

10.1.1 General Awareness

The main purpose for general awareness-raising community engagement is to generate awareness around and support for HPTN 096 to raise the level of community acceptability. Community engagement for the purposes of general awareness-building during the pilot will focus on the creation of awareness which will be demonstrated through community acceptability of the study. These activities are separate from how community engagement will be conducted for the specific study components and the cross-sectional assessment (described further in sections below). The primary general community awareness pilot outcome measure will be the formation and utilization of a community advisory group (CAG).

The CAG will meet monthly to discuss stakeholder engagement strategies. CAG members will provide high-level input and guidance to the HPTN 096 study team related to community awareness and acceptability throughout the pilot. The CAG will bring a diversity of perspectives and expertise, connecting issues and opportunities across stakeholder engagement, agencies, and local stakeholder sectors. The CAG will meet 8-10 times over the course of the pilot process. The CAG understands there is no one size fits all community awareness strategy, so each individual CAG member will work locally to keep established relationships open and find ways to create new stakeholder engagement and awareness opportunities for HPTN 096.

The community strategy group (CSG) will meet on an ongoing basis and serve as an advisory group to the protocol team and the CAG about stakeholder engagement activities and planning for HPTN 096. The meetings will also provide an opportunity for CSG members to give input on what is most useful and help with gap analysis, strategy selection, and implementation of future stakeholder engagement-awareness planning.

Method of Engagement	Stakeholders
(1) Leadership Briefings	Community Ambassadors and Gate Keepers
(2) CSG and CAG Networking	External Local Community Audiences
(3) Stakeholder/Black MSM Feedback and/or Listening Sessions	Various Audiences

10.2 Component-Specific Community Engagement Activities and Pilot Outcomes Measures

Each study component will involve tailored community engagement activities for the purposes of gaining participation in, awareness of, or acceptability for each component. These community engagement activities are largely integrated into the activities of the study component itself, and as such, the success of community engagement as it relates to specific components will be assessed from a subset of pilot outcome measures already identified for each component. Specific engagement activities and their purpose for each component, as well as the pilot outcome measures that will serve as measures of community engagement success, are described in the sub-sections below.

10.2.1 Health Equity

As described in the main protocol and in Pilot Appendix Section 4.0, community engagement activities for the Health Equity component will be focused on partnering with local CBOs to establish community coalitions in each intervention community. The success of community engagement efforts for the Health Equity pilot will be measured by the following Health Equity pilot outcome measures (as described further in Pilot Appendix Section 4.0):

- Agreement in place with local CBO to serve as implementing partner in each pilot intervention community
- Community coalition established in each pilot intervention community and length of time required for establishment
- Number/types of engagement activities used in the formation of the community coalitions.
- Memoranda of Agreement signed by local CBO implementing partner organizations in each non-pilot intervention community declaring intention to establish coalitions once the full implementation period begins.

10.2.2 Social Media Influencers

As described in the main protocol and in Pilot Appendix Section 5.0, community engagement activities for the SMI component will be focused on identifying and vetting appropriate SMI for selection as study SMI. SMI activities such as providing messaging on HIV-related topics, as well as the promotion of other study components, will be considered a form of community engagement as well. The success of community engagement efforts for the SMI pilot will be

measured by the following SMI pilot outcome measures (as described further in Pilot Appendix Section 5.0):

- Number of SMIs in each region/community
- Metrics of social media engagement, including the following:
  - Clicks on links/videos
  - Number of views per post
  - Number/types/demographics of followers of SMIs
  - Number and types of reposts/retweets
  - Types of content developed

10.2.3 Intersectional Stigma Reduction

As described in the main protocol and in Pilot Appendix Section 6.0, community engagement activities for the Intersectional stigma reduction component will be focused on recruiting healthcare facilities who service Black MSM and relationship building with targeted facilities to gain their agreement to participate in the study.

The success of community engagement efforts for the Intersectional Stigma Reduction pilot will be measured by the following Intersectional Stigma Reduction pilot outcome measures (as described further in Pilot Appendix Section 6.0):

- Number and types of participating pilot HCF
- Number of Letters of Intent signed with HCFs in all intervention communities by the end of the pilot period, and types of HCF agreeing to participate

10.2.4 Peer Support

As described in the main protocol, community engagement methods will be used for promotion of the peer support program, and also identification and recruitment of peer support workers. Community engagement activities will be used to educate and inform the public about the peer support program and raise awareness of the program portal/website. Word of mouth referrals and advertisements about the program may be used by peers or/and community partners and more broadly through their networks. Community engagement activities may also leverage invaluable networks such as the CAG members and other community partners to identify and recruit peer supporters and program participants.

The success of community engagement efforts for the Peer Support Component pilot will be measured by the following Peer Support pilot outcome measures (as described further in Pilot Appendix Section 7.2):

- Number of peer support workers recruited and trained
- Number of clients who access the program, with capture of limited sociodemographic characteristics and frequency of use and type of support sought
- Measurement of where clients learned about the platform

10.3 Cross-Sectional Assessment Community Engagement Activities and Pilot Outcome Measures

During the pilot, the baseline cross-sectional assessment is expected to be conducted in the four pilot communities, as described in Pilot Appendix Section 8.0. One hundred Black MSM in each pilot community (for a total of 400) will be recruited via starfish sampling, which combines venue-based and respondent-driven sampling. The starfish methodology is designed to sample a random, and thus representative, segment of a population. Direct recruitment into the study could potentially bias the sample and impact the results. Thus, community engagement will support the starfish methodology in two, less direct, ways: 1) it may advertise and promote venues and events where sampling may take place - but will not advertise that that study sampling may take place at these venues/events; and 2) it will educate the community about the study and its purpose, so that if an individual is approached by a staff member or peer, they will be more willing to engage in the research. Ways that this type of community engagement may take place may include, but are not limited to, the following:

- Online ads and social networking
- Working with partner organizations
- Partner health professionals
- Engaging community gate keepers (i.e., house-ball parents, community advocates, trusted organizations, etc.)
- African American MSM (AAMSM) professional networks

Successful recruitment of Black MSM from the four pilot communities into the baseline cross-sectional assessment will be the primary community engagement measure of success for the pilot period.

11.0 STATISTICAL CONSIDERATIONS

11.1 Inclusion of Pilot Data into Overall Study Analysis

The cross-sectional assessment in the pilot communities will constitute the baseline assessment for those communities and the pilot intervention period will be included as part of the first year of the study intervention period. We expect that the intervention period (the time between the baseline and post-intervention cross-sectional assessments) will be the same (3 years) in the pilot communities as in the non-pilot communities. However, this decision will be reviewed in an interim analysis of the data collected during rollout of the pilot compared to the data collected during the first year of rollout in the non-pilot communities (see Pilot Appendix Section 11.2).

Section 12.8 of the main protocol describes analyses based on all 8 community pairs; that is, we include the 2 pilot community pairs in the primary analysis. However, we will also perform a sensitivity analysis in which the primary analyses (Protocol Section 12.8.2) will be repeated without the pilot communities.

11.2 Inclusion of Staggered Start into Overall Study Analysis

HPTN 096 is designed as a matched-pairs study and all analyses will incorporate this aspect of the design. In a matched-pairs study, each intervention community is compared with its matched-pair control community and not with other control communities (see protocol sections 12.8.2 and 12.8.3 for details). Therefore, provided that each community within a pair starts and ends study participation at the same time, any overall time trends (e.g. a secular increase in PrEP use over time) will cancel out in the analysis, even if different pairs start and end the study at different times. Thus, the proposed structure with two pairs (4 communities) piloting the intervention and the remaining 6 pairs (12 communities) starting approximately a year later will not require any change to the analytic plan. This approach assumes that the incremental effect of the intervention is constant over time and that the nature of the intervention does not change substantially between the pilot and the full study.

The inclusion of a pilot phase does assume that a three-year intervention period in the pilot communities will result in an equivalent intervention effect as the three-year intervention period in the non-pilot communities. However, this may depend on the intensity and coverage of the intervention during the pilot period compared to the intensity and coverage of the intervention during the first year of study implementation in the non-pilot communities. Since these issues are poorly understood at this time, and likely will not be understood until after the first year of the intervention in the non-pilot communities, we will revisit this issue in a formal interim review of the data after the first year of the intervention in the non-pilot communities. At that time, the protocol team may decide to extend the intervention period in the pilot communities for an additional period (6-9 months) to allow for slow intervention roll-out in these communities. Importantly, any such decision will be made solely on the basis of process data of intervention delivery and not using any outcome data.

11.3 Provision of HIV Surveillance and PrEP Prescription Data

One of the co-primary objectives of HPTN 096 is being assessed by examining viral suppression data from the CDC's HIV surveillance system. During full implementation, the CDC will provide preliminary viral suppression data to the protocol team four months after the year of interest has ended. As such, one of the pilot outcome measures will be the transfer of viral suppression data as outlined in the main study protocol for the four pilot communities. These data should contain 2021 information and be provided to the protocol team by May 2022.

For the other co-primary objective of HPTN 096, commercially available PrEP prescription data from AIDSVu will be used for supportive analysis. To keep acquisition of these data in the same timeframe as the viral suppression data, during full implementation these data will be expected four months after the year of interest, which may or may not coincide with a calendar year, has ended. As such, another pilot outcome measure will be the acquisition of 2021 PrEP prescription data for the four pilot communities by May 2022.

11.4 Summaries of Pilot Data

The SDMC will develop a set of reports – similar to the reports typically developed for a Study Monitoring Committee review – that summarize enrollment in the cross-sectional survey,

demographic characteristics of the sample, metrics of intervention delivery, data completeness and completeness of sample collection for laboratory assays in the pilot communities. Social harms associated with study participation and protocol deviations will also be summarized. To ensure that the necessary data transfer processes are functioning correctly, baseline data on viral suppression for the pilot communities will be downloaded from the CDC and summarized. Similarly, PrEP prescription data at baseline will be downloaded from AIDSVu for the pilot communities and summarized. These reports will be available for review near the end of the pilot period.

11.5 Comparison of AMIS and Pilot Surveys

A subset of the questions asked on the baseline cross-sectional survey will also be asked in the AMIS surveys (see Pilot Appendix Section 8.2). We will summarize the AMIS results for all 16 communities and will descriptively compare the results for the common questions between the AMIS surveys and the baseline cross-sectional survey in the four communities included in the HPTN 096 pilot.

12.0 TRANSITION FROM PILOT TO FULL IMPLEMENTATION

As described in the Pilot Appendix Section 2.0 and shown in Pilot Appendix Figure 1, the pilot will represent the start of study implementation in the two pilot matched pairs, with the remaining six matched pairs expected to begin full study implementation approximately one year after the start of the pilot. As such, it is expected that study implementation in the pilot communities will continue for a full three-year implementation period, with no pause between the conclusion of the pilot period and the beginning of full implementation. This continuity is critical to the success of the integrated strategy, as well as to the partnerships, trust and relationships built in study communities. The transition from the pilot to full implementation in the pilot communities will reflect the organic growth and implementation scale-up of the integrated strategy that is naturally expected to happen in all study communities. In order to facilitate this seamless transition between pilot and full implementation, indicators of feasibility success will be assessed on a continuous basis throughout the pilot period with formal (e.g., Study Monitoring Committee (SMC) study reports) and ongoing informational updates provided to the study sponsor. It is expected that the study protocol will need to be amended to incorporate lessons learned from the pilot, and this will occur once the pilot period concludes but prior to full implementation beginning in the non-pilot communities. Study activities in pilot communities are not expected to be paused during this time. As described in Pilot Appendix Section 2.3, during the pilot period, activities will take place in non-pilot communities in preparation for study implementation. These activities will also continue in the time period between the formal end of the pilot period and the beginning of full implementation in the non-pilot communities.

APPENDIX IIC: SAMPLE INFORMED CONSENT FORMS FOR ADULTS AND ASSENT FORMS FOR INDIVIDUALS UNDER AGE 18

APPENDIX IIC-I: SAMPLE ICF FOR PILOT PEER SUPPORT

HPTN 096
Getting to Zero among Black Men who have Sex with Men (MSM) in the American South: Testing the Efficacy of an Integrated Strategy

FINAL Version 3.o
3 August 2023
DAIDS Document ID: 38561

SPONSORED BY: Division of AIDS, US National Institute of Allergy and Infectious Diseases, US National Institutes of Health.

PRINCIPAL INVESTIGATOR: [Add Name]

PHONE: [Insert Number]

INTRODUCTION
You are being asked to take part in a research study, entitled HPTN 096 or 'Getting to Zero among Black Men who have Sex with Men (MSM) in the American South.' This study is being done by the HIV Prevention Trials Network (HPTN).

Before you decide whether to take part in the study, this form explains the purpose of the study, the risks and benefits, and what will happen to you.

1. You should know key information about this study before you join.

- You are being asked to join this study because you self-identify as a Black man who has sex with men (MSM) and are at least 15 years old.
- Taking part in this study is your choice. You can agree to be in the study today or not. If you agree, you can change your mind and leave the study at any time.
- If you decide not to take part in this study at any time, it will not affect the regular care that you receive in your community.
- The study will first be done in a subset of communities. During this time, the study team will identify problem areas and find ways to improve the programs before conducting the full study.
- You will be in the part of the study where you will be connected with a peer support worker who can provide virtual support for HIV-related issues. They can give you information about testing for HIV and other infections passed through sex, how to take medication to prevent or treat HIV, and how to find local resources that are friendly to Black MSM.

- You may benefit from the help you get from the peer support worker. The program may continue for up to three years and if so, you will be able to continue to receive this support if you choose.

ABOUT THE STUDY

2. The overall study is testing four programs to reduce HIV in Black MSM.

Sixteen communities are participating in this research study. In eight communities, various programs will be put in place. In the other communities, these programs will not be available.

The four programs are described below:

- One program will provide training to medical providers. This training seeks to make their clinics friendlier towards Black gay, bisexual and other men who have sex with men.
- The second program seeks to work with community groups to help Black MSM overcome barriers to preventing and treating HIV.
- The third program will use social media to raise awareness about HIV testing, PrEP use and provide information about HIV care and prevention.
- The last program provides peer support and health education for those living with and without HIV. This program is described in more detail in the remainder of this form.

We hope these programs will reduce barriers to HIV prevention and care and decrease the number of Black men who get HIV.

Before carrying out these programs in all eight communities, they will be put in place in two communities, for about nine months. During this time, the study team will work to find ways to improve all the programs before starting the programs in the remaining communities.

3. You are being asked to be in the part of the study that is testing virtual peer support.

You will be offered peer support and HIV-related health information. We expect up to 15,000 Black men who have sex with other men to use the program during the full study.

You will be connected with peer support workers, through a third-party platform (such as Zoom), who can help you in many ways. They can help you decide if you should get an HIV test and where to get one. If you have HIV, they will talk with you about getting medical care and taking medication to treat HIV. They can also help with how you can tell other people about your status. If you don't have HIV, the peer worker can help you with ways to protect yourself from getting HIV and STIs. This includes how to get and use pre-exposure prophylaxis (PrEP), which is medication that can protect you from getting HIV. The peer support workers may be able to help you with other problems and they are always willing to just listen.

If you agree to be a part of this program, you may interact with the peer support worker one-on-one discussion. On rare occasions and only if agreeable to you and the peer support worker, an in-person support session may be provided. You may be asked some questions about your experience working with the peer support worker. For example, you will be asked whether you were satisfied with the support you received. You may also be asked if you made any informed decisions as it relates to HIV prevention and care in response to the support you received (for example, did you get tested for HIV?).

RISKS OF THE STUDY

4. There may be risks to being in this study.

- Sensitive questions or topics may be discussed. This may occur during conversations with your peer support worker.
- Discussing your sexual behavior and ways to protect against HIV and STIs may make you uncomfortable.
- Only people in the study can access this support. We ask that you not share your personal information with anyone else to ensure your information and the information of others who are a part of the program stay private.
- It may be possible that others will learn you have joined this study and they may treat you unfairly. For instance, your family members or friends could treat you unfairly because they think you are involved in a study about HIV. They may assume that you have HIV. The peer support workers can help you deal with any feelings or questions you have.
- There is a possibility that you may exceed your data plan limit on your personal device (cell phone or tablet) if you use it to access the program and may have to pay extra for that.
- You are asked to follow the rules of the study. If you or others share inappropriate information, your participation in the program may be stopped.
- As part of this study, you may be required to use one or more of the following: a phone or computer to complete surveys about your experience with the program. You may be asked to provide limited personal and sociodemographic information (such as your name, age, ethnicity, phone number, email address, etc.) that may be shared with the peer support workers and researchers conducting this study.
- Additionally, there may be unknown risks.

BENEFITS OF THE STUDY

5. You may benefit from the help you get from the peer support worker.

The peer support worker may give you information that you find useful. It may also make you feel better to have someone to talk to. What we learn from you may help us learn more about

HIV in your community. This information may lead to better ways to prevent and treat HIV in the future.

OTHER INFORMATION ABOUT THE STUDY

6. There may be other ways to get peer support in your community.

You will have access to a website that contains information about organizations that provide HIV care, HIV prevention, PrEP and other services available in your community.

7. We will let you know of any new information that becomes available that may make you change your mind about continue participating in the study.

8. You may be taken out of the study without your consent.

We may take you out of the study if you fail to follow the rules of the program. We may also take you out of the study if the people who fund the study (NIH), conduct the study (HPTN) or review the study (institutional review board [IRB]) stop the study.

9. **You will receive xx for conducting an initial support session.**

You will not receive compensation for participating in subsequent peer support sessions. You may receive xx for responding to brief surveys about your experience using the peer support program.

10. We will do our best to protect your private information.

We will make every effort to protect and ensure your privacy while in the program.

We will make every effort to protect your private information. We will only collect enough of your personal and sociodemographic information (such as your name, age, ethnicity, phone number, email address, etc.) to connect you with a peer support worker. You will get a unique study identification number and your information will only be linked to a code, not your name or any other identifying information. The HPTN and people who work for them such as the program managers and peer support workers may review your sessions to ensure the program is being done properly and for supervision of the peer support workers. It may also be reviewed by the organization that funds this study, such as the National Institutes of Health (NIH). Any Institutional Review Board(s) (IRB) overseeing this study, and US Office for Human Research Protections are allowed to review the information you provide to the study. Your records will be kept for at least 3 years after the study ends, or longer if local regulations require. However, when regulations allow it, all sessions will be deleted.

All peer support workers will be trained and agree not to reveal any sensitive information you share with them.

If we learn that you or someone else is in danger, we must take steps to keep you and others safe. For example, if you tell us that you plan to hurt or kill yourself or someone else, or if you tell us that someone is abusing or neglecting you. This may mean asking for your personal information and sharing this information with the proper authorities (hospital, police, or social services).

The researchers in this study will do everything they can to protect your privacy. We have obtained a "Certificate of Confidentiality" from NIH which can be used to legally refuse to give information that would identify you to others that are not a part of the study. For example, researchers can say "No" to a court that is trying to get information about you. But the courts can make researchers give information about you to prevent serious harm to you or others.

This certificate does not stop you, or people close to you, from telling others about your participation in the study. So, you and people close to you need to protect your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

11. If you get sick or injured during the study, let us know right away.

It is unlikely that you will be injured as a result of being in the study. If you are injured, please tell us right away. If your injuries require treatment, you may or may not have to pay for this treatment. There is no program to pay money or give other forms of compensation for such injuries from the NIH. You do not give up any legal rights by signing this consent form.

12. Who to contact about this study.

During the study, if you experience any problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact please contact the investigator listed on the first page of this document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

By mail:
Study Subject Adviser
Advarra IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
or call toll free: 877-992-4724
or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00056458.

SIGNATURE PAGE

HPTN 096
Getting to Zero among Black MSM in the American South:
Testing the Efficacy of an Integrated Strategy

FINAL Version 3.0
3 August 2023
INFORMED CONSENT/ASSENT FOR PEER SUPPORT

If you agree to the information in this form and you voluntarily agree to join the study, please print and sign your below. A copy of this consent form will be available to you at any time.

_____
Participant Name (print first and last name)

_____
Date

_____
Email Address (to receive an electronic copy of the signed consent form)

_____
Code word or phrase for verification purposes
The peer supporter will ask you for this prior to your first session.

Do you voluntarily agree to join the study?
_____Yes
_____No

_____
Participant Signature

Checkbox: I certify that all of my information in the document above is correct. I understand that clicking "Submit" will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

APPENDIX IIC-II: SAMPLE INFORMED CONSENT FORM FOR ADULTS AND ASSENT FOR INDIVIDUALS AGES 15 TO AGE OF MAJORITY FOR PILOT BASELINE CROSS-SECTIONAL ASSESSMENTS WITH LDMS (COMMUNITIES WITH LOCAL LDMS LABORATORY)

HPTN 096
Getting to Zero among Black Men who have Sex with Men (MSM) in the American South: Testing the Efficacy of an Integrated Strategy

FINAL Version 3.0
3 August 2023
DAIDS Document ID: 38561

SPONSORED BY: Division of AIDS, US National Institute of Allergy and Infectious Diseases, US National Institutes of Health.

INVESTIGATOR OF RECORD: [Add Name]

PHONE: [Insert Number]

INTRODUCTION
You are being asked to take part in a research study, entitled HPTN 096 or 'Getting to Zero among Black Men who have Sex with Men (MSM) in the American South.' This study is being done by the HIV Prevention Trials Network (HPTN).

Before you decide whether to take part in the study, this form explains the purpose of the study, the risks and benefits, and what will happen to you. You will be offered a copy of this consent form to keep.

1. You should know key information about this study before you join.

- You are being asked to join this study because you self-identify as a Black man who has sex with men (MSM) and are at least 15 years old.
- Taking part in this study is your choice. You can agree to be in the study today or not. If you agree, you can change your mind and leave the study at any time. If you choose not to join or to leave the study, you can still receive services from the field team in the future.
- The study will first be done in a subset of communities. During this time, the study team will identify problem areas and find ways to improve the programs before conducting the full study.
- You will be in the part of the study where we are measuring how many Black men like you have HIV. We are also checking to see how many are taking medication to treat or prevent HIV. Answering these questions will tell us if the other parts of the study are working to decrease HIV in some communities in the southern US.

- You will be offered an HIV rapid test, a home test kit or a coupon to obtain a home test kit. You do not have to take the rapid or home test kit or the coupon to be in the study.
- You will be asked to provide a blood sample from your arm and to answer two surveys – one is short, and one is longer. You will be asked to do the short survey today, but you can do the longer one later.
- You may also be offered coupons to give to your friends who are Black MSM. These coupons will allow your friends to participate in the study too.
- It will take about 30-60 minutes to be in the study today, depending on whether you choose to complete the longer survey now or later.
- It may hurt a little to give blood. Some of the questions in the survey are about sex or other topics that may make you feel uncomfortable. By participating in this study, people may think you have HIV, even if you don't.
- You may not receive any direct benefits from being in this study. However, what we learn from you may help us learn more about HIV in your community. This information may lead to better ways to prevent HIV in the future.
- You will receive some money if you give blood, complete the questions and if you recruit others to the study.

ABOUT THE STUDY

2. The overall study is testing four programs to reduce HIV in Black MSM.

Sixteen communities are participating in this research study. In eight communities, various programs will be put in place. In the other communities, these programs will not be available. The four programs are described below:

- One program will provide training to medical providers. This training seeks to make their clinics friendlier towards Black gay, bisexual and other men who have sex with men.
- The second program seeks to work with community groups to help Black MSM overcome barriers to preventing and treating HIV.
- The third program will work with popular people on social media to raise awareness about HIV testing, PrEP use and provide information about HIV care and prevention.
- The last program provides peer support and health education for those living with and without HIV.

We hope these programs will reduce barriers to HIV prevention and care and decrease the number of Black men who get HIV.

Before carrying out these programs in all eight communities, they will be put in place in two communities, for about nine months. During this time, the study team will work to find ways to improve all the programs before starting the programs in the remaining communities.

3. You are being asked to be in the part of the study to find out if the four programs are decreasing HIV in some communities in the southern US.

This part of the study is called the cross-sectional assessment. During the study, there will be two cross-sectional assessments. The first one will take place before the programs start, and the second one will take place after the programs end. You are being asked to take part in the first (pilot) assessment.

About 400 Black MSM will participate in the first (pilot) assessment. About 100 will be from your community.

The purpose of both assessments is to find out how many Black MSM in your community have HIV. We are also checking to see how many are taking medication to treat or prevent HIV. Finally, we will ask questions about your life and opinions.

If you decide not to be in the study, there is no penalty and there will be no impact on any future healthcare.

4. You will be offered an HIV rapid test. You will also be offered a home test kit or a coupon to obtain a home test kit.

You will be offered an HIV rapid test. You will also be offered a home test kit or a coupon to obtain a home test kit locally. You don't have to take the HIV rapid test, or the home test kit or coupon to be in the study. The home kit will include instructions on how to take the test and what your results mean. If you have a positive test result, the kit provides information on how to get counseling and care. It is okay to take the kit or coupon being offered and give it to someone else who you feel could benefit from an HIV test. You can take up to two HIV mail-in test kits or coupons. The results of these tests are not part of the study and will not be entered into the study database.

5. We will take some blood from you.

We will take blood from your arm.

You will be asked to provide up to 40 mL of blood from your arm. This is about 8 teaspoons of blood. This blood will be used to check for HIV. If you have HIV, this blood will also be used to check how much virus is in your blood, whether you are taking medications to treat HIV, and whether the virus is resistant to drugs used treat HIV. This blood will also be used to estimate the number of new HIV infections in your community and to see how HIV spreads in the community. If you do not have HIV, this blood will be used to check if you are taking any medications to prevent HIV. If you have HIV, this sample may be used to estimate the number of new HIV infections in your community. Regardless of whether you have HIV or not, this blood may be used for tests about SARS-CoV-2 or other related viruses.

This testing will be performed at the HPTN Laboratory Center, or at laboratories selected by the HPTN Laboratory Center. Results from this testing will not be returned to you or the local study

team. Your blood samples will be identified with a study number but will not include any of your personal information. If you do not give permission to store your blood long term for future research, any leftover blood will be destroyed after the study required testing is completed. Your blood samples will never be used for commercial profit.

6. You will complete two surveys – one short and one long

You will be asked to complete two surveys – one short and one longer. You will complete the short one at the same time as the blood draw. You can complete the longer one today, or later. In the surveys, we will ask some basic questions about yourself (like your age and race). We will ask you what you know about this study, your health, your social support, how others treat you related to being gay, Black or living with HIV and your access to healthcare. We will also ask you questions related to HIV (like testing and what you know about how to prevent infection).

If you decide to do the longer survey later, we will ask you for your phone and email address so that we may contact you with reminders to do this survey.

7. We may ask you to invite others to join the study.

You may be offered up to three coupons to give to your friends and other people you know who self-identify as a Black MSM and are at least 15 years old that may be interested in the study. If the people who you give coupons are eligible and chose to participate in the study, you will receive some money. If you decide to take coupons to give to other people, we will ask you for your phone number or email so that we can give you this money.

8. It will take about 30-60 minutes to be in the study today.

It may take up to 30 minutes to provide your consent, have your blood drawn, answer the short questionnaire, and receive the coupons and your money. It may take up to 30 minutes to answer the longer survey, which you can do today or later.

9. Some of your blood may be left over at the end of the study and may be used for future research with your permission.

Some of your blood may be left over after all of the study tests are completed. If you agree, your samples may be stored and used for future research. If you agree, your samples and related health information will be stored safely and securely.

Only approved researchers will be able to use these samples and health information. Some researchers will need to have access to these samples to store them and keep track of where they are, but these people will not have information that directly identifies you.

There is no time limit on how long your samples will be stored. We do not yet know the specific type of testing that will be done with these samples. They may be used to check that certain laboratory tests are performed correctly. We do not plan to do any testing of your genes on stored samples. Any future testing that is not related to the goals of this study will have to be approved by an Institutional Review Board/Ethics Committee (IRB/EC).

You can still be in this study if you decide that we cannot store your leftover blood. You can change your mind about storing and using these samples for future tests at any time by writing to the person in charge of this study. We will then destroy the leftover samples. But researchers will not be able to destroy samples or information from research that is already started.

Please indicate by providing your initials in the spaces below if you agree to long-term storage and future testing of leftover blood samples.

PARTICIPANT INITIALS	
Initials Date	I DO agree to allow my leftover blood to be stored and used in future research studies.
Initials Date	I DO NOT agree to allow my leftover blood to be stored and used in future research studies.

RISKS OF THE STUDY

10. There may be risks to being in this study.

- If you decide to take and use the HIV mail-in test kit, you may feel nervous waiting for your test result. If the test shows that you might have HIV, you may worry about your health and future.
- When we draw your blood, we will stick a needle into your arm. This may hurt for a moment, and you may have a bruise afterwards. You may feel lightheaded, or in rare cases, you may faint. There is a small chance that you could get an infection at the place the needle went into your arm.
- Some of your blood will be tested for HIV. The study staff may be required by law to report the result of these tests to the local health authority.
- Some of the questions we ask you may make you feel uncomfortable or embarrassed. However, you will be answering these questions on a tablet, a computer or your phone, so you will not have to talk about your answers with anyone. You can skip questions that make you uncomfortable.
- If you take the longer survey later, we suggest that you answer the questions in a private place. This way, others will not see your answers.
- If others find out you are in the study, they may treat you unfairly. For example, your friends or family may treat you unfairly because they think that being in the study means that you have HIV.
- Additionally, there may be unknown risks.

BENEFITS OF THE STUDY

11. There may be no direct benefit to you by being in the study.

However, what we learn from you may help us learn more about HIV in your community. This information may lead to better ways to prevent HIV in the future. You will have the choice to receive a free HIV mail-in test kit or coupon to obtain a kit. You can use this kit yourself or give it to someone else who you think could benefit from an HIV test.

OTHER INFORMATION ABOUT THE STUDY

12. There are other ways to get HIV testing in your community.

Please ask the study staff if you would like more information about local HIV testing.

13. You may be withdrawn from the study without your consent.

This may happen if you fail to follow the instructions given by the study staff. We may also take you out of the study if the people who fund the study (NIH), conduct the study (HPTN) or review the study (institutional review board [IRB]) stop the study.

14. There is no cost to you to be in this study, and you will receive some money

We will give you up to $xx for being in the study.

When you provide the blood draw and complete the short survey, you will receive $xx. When you complete the longer survey, you will receive: $xx. If someone who you provide a coupon to participates in the study, you will receive: $xx. If all three people who you give a coupon to bring back their coupons, you will receive a total of $xx ($xx for each person).

15. We will let you know if any new information becomes available that may make you change your mind about participating in the study.

16. We will do our best to protect your private information.

We will make every effort to protect your private information, but we cannot guarantee absolute confidentiality. We will only collect enough of your personal information to ensure that you only participate in the study one time, to provide reminders about longer survey completion as needed, and to give you your money if you recruit others to the study. None of this information will be put into the study database, and it will be kept in a locked location. In the database, your information will only be linked to a code, not your name or any other identifying information. All study staff are trained and agree not to reveal any private information you share with them. Any publication of this study will not use your name or identify you personally.

The information you provide may be reviewed to ensure the assessment is being done properly. This information may be reviewed by the HPTN and people who work for them such as the

study staff. It may also be reviewed by the organization that funds this study, National Institutes of Health (NIH), its contractors and study monitors. Any Institutional Review Board(s) (IRB) overseeing this study, and US Office for Human Research Protections are allowed to review the information you provide to the study. Your records will be kept for at least 3 years after the study ends, or longer if local regulations require. Your records will be destroyed when regulations allow it.

The researchers in this study will do everything they can to protect your privacy. We have obtained a "Certificate of Confidentiality" from NIH which can be used to legally refuse to give information that would identify you to others that are not a part of the study. For example, researchers can say "No" to a court that is trying to get information about you. But the courts can make researchers give information about you to prevent serious harm to you or others.

This certificate does not stop you, or people close to you, from telling others about your participation in the study. So, you and people close to you need to protect your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

17. If you get sick or injured during the study, let us know right away.

It is unlikely that you will be injured as a result of being in the study. If you are injured, the study staff will help you right away. You may or may not have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries from the NIH. You do not give up any legal rights by signing and dating this consent form.

18. Who to contact about this study.

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact [add the name of the IoR] at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

By mail:
Study Subject Adviser, Advarra IRB
6940 Columbia Gateway Drive, Suite 110. Columbia, MD 21046
or call toll free: 877-992-4724
or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: (insert PRO number)

SIGNATURE PAGE

HPTN 096
Getting to Zero among Black MSM in the American South:
Testing the Efficacy of an Integrated Strategy

FINAL Version 3.0
3 August 2023
INFORMED CONSENT/ASSENT FOR CROSS-SECTIONAL ASSESSMENT

If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below.

_____	_____
Participant Name (print)	Participant Signature and Date
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature and Date
_____	_____
Witness Name (print) (As appropriate)	Witness Signature and Date

APPENDIX IIC-III: SAMPLE INFORMED CONSENT FORM FOR ADULTS AND ASSENT FOR INDIVIDUALS AGES 15 TO AGE OF MAJORITY FOR PILOT BASELINE CROSS-SECTIONAL ASSESSMENTS (COMMUNITIES WITHOUT LOCAL LDMS LABORATORY)

HPTN 096
Getting to Zero among Black Men who have Sex Men (MSM) in the American South: Testing the Efficacy of an Integrated Strategy

FINAL Version 3.0
3 August 2023
DAIDS Document ID: 38561

SPONSORED BY: Division of AIDS, US National Institute of Allergy and Infectious Diseases, US National Institutes of Health.

INVESTIGATOR OF RECORD: [Add Name]

PHONE: [Insert Number]

INTRODUCTION
You are being asked to take part in a research study, entitled HPTN 096 or 'Getting to Zero among Black Men who have Sex with Men (MSM) in the American South.' This study is being done by the HIV Prevention Trials Network (HPTN).

Before you decide whether to take part in the study, this form explains the purpose of the study, the risks and benefits, and what will happen to you. You will be offered a copy of this consent form to keep.

1. You should know key information about this study before you join.

- You are being asked to join this study because you self-identify as a Black man who has sex with men (MSM) and are at least 15 years old.
- Taking part in this study is your choice. You can agree to be in the study today or not. If you agree, you can change your mind and leave the study at any time. If you choose not to join or to leave the study, you can still receive services from the field team in the future.
- The study will first be done in a subset of communities. During this time, the study team will identify problem areas and find ways to improve the programs before conducting the full study.
- You will be in the part of the study where we are measuring how many Black men like you have HIV. We are also checking to see how many are taking medication to treat or prevent HIV. Answering these questions will tell us if the other parts of the study are working to decrease HIV in some communities in the southern US.

- You will be offered an HIV rapid test, a home test kit or a coupon to obtain a home test kit. You do not have to take the rapid or home test kit or the coupon to be in the study.
- You will be asked to provide a blood sample from your arm and answer two surveys – one is short, and one is long. You will be asked to do the short survey today, but you can do the long one later.
- You may also be offered coupons to give to your friends who are Black MSM. These coupons will allow your friends to participate in the study too.
- It will take about 30-60 minutes to be in the study today, depending on whether you choose to complete the longer survey now or later.
- It may hurt a little to give blood. Some of the questions in the survey are about sex or other topics that may make you feel uncomfortable. By participating in this study, people may think you have HIV, even if you don't.
- You may not receive any direct benefits from being in this study. However, what we learn from you may help us learn more about HIV in your community. This information may lead to better ways to prevent HIV in the future.
- You will receive some money if you give blood, complete the questions and if you recruit others to the study.

ABOUT THE STUDY

2. The overall study is testing four programs to reduce HIV in Black MSM.

Sixteen communities are participating in this research study. In eight communities, various programs will be put in place. In the other communities, these programs will not be available. The four programs are described below:

- One program will provide training to medical providers. This training seeks to make their clinics friendlier towards Black gay, bisexual and other men who have sex with men.
- The second program seeks to work with community groups to help Black MSM overcome barriers to preventing and treating HIV.
- The third program will work with popular people on social media to raise awareness about HIV testing, PrEP use and provide information about HIV care and prevention.
- The last program provides peer support and health education for those living with and without HIV.

We hope these programs will reduce barriers to HIV prevention and care and decrease the number of Black men who get HIV.

Before carrying out these programs in all eight communities, they will be put in place in two communities, for about nine months. During this time, the study team will work to find ways to improve all the programs before starting the programs in the remaining communities.

3. You are being asked to be in the part of the study to find out if the four programs are decreasing HIV in some communities in the southern US.

This part of the study is called the cross-sectional assessment. During the study, there will be two cross-sectional assessments. The first one will take place before the programs start, and the second one will take place after the programs end. You are being asked to take part in the first (pilot) assessment.

About 400 Black MSM will participate in the first (pilot) assessment. About 100 will be from your community.

The purpose of both assessments is to find out how many Black men in your community have HIV. We are also checking to see how many are taking medication to treat or prevent HIV. Finally, we will ask questions about your life and opinions.

If you decide not to be in the study, there is no penalty and there will be no impact on any future healthcare.

4. You will be offered an HIV rapid test. You will also be offered a home test kit or a coupon to obtain a home test kit.

You will be offered a HIV rapid test. You will also be offered a home test kit or a coupon to obtain a home test kit locally. You don't have to take the HIV rapid test, or the home test kit or coupon to be in the study. The home kit will include instructions on how to take the test and what your results mean. If you have a positive test result, the kit provides information on how to get counseling and care. It is okay to take the kit or coupon being offered and give it to someone else who you feel could benefit from an HIV test. You can take up to two HIV mail-in test kits or coupons. The results of these tests are not part of the study and will not be entered into the study database.

5. We will take some blood from you.

We will take blood from your arm.

You will be asked to provide 20 mL of blood from your arm. This is about 4 teaspoons of blood. This blood will be used to check for HIV. If you have HIV, this blood will also be used to check how much virus is in your blood. If you have HIV, this sample may be used to estimate the number of new HIV infections in your community. If you do not have HIV, this sample will be used to check if you are taking any medications to prevent HIV.

This testing will be performed at the HPTN Laboratory Center, or at laboratories selected by the HPTN Laboratory Center. Results from this testing will not be returned to you or the local study team. Your blood samples will be identified with a study number but will not include any of your personal information. If you do not give permission to store your blood long term for future research, any leftover blood will be destroyed after the study required testing is completed. Your blood samples will never be used for commercial profit.

6. You will complete two surveys – one short and one long

You will be asked to complete two surveys – one short and one long. You will complete the short one at the same time as the blood draw. You can complete the longer one today, or later. In the surveys, we will ask some basic questions about yourself (like your age and race). We will ask you what you know about this study, your health, your social support, how others treat you related to being gay, Black or living with HIV and your access to healthcare. We will also ask you questions related to HIV (like testing and what you know about how to prevent infection).

If you decide to do the longer survey later, we will ask you for your phone and email address so that we may contact you with reminders to do this survey.

7. We may ask you to invite others to join the study.

You may be offered up to three coupons to give to your friends and other people you know who self-identify as a Black MSM and are at least 15 years old that may be interested in the study. If the people who you give coupons are eligible and chose to participate in the study, you will receive some money. If you decide to take coupons to give to other people, we will ask you for your phone number or email so that we can give you this money.

8. It will take about 30-60 minutes to be in the study today.

It may take up to 30 minutes to provide your consent, have your blood drawn, answer the short questionnaire, and receive the coupons and your money. It may take up to 30 minutes to answer the longer survey, which you can do today or later.

9. Some of your blood may be left over at the end of the study and may be used for future research with your permission.

Some of your blood may be left over after all of the study tests are completed. If you agree, your samples may be stored and used for future research. If you agree, your samples and related health information will be stored safely and securely.

Only approved researchers will be able to use these samples and health information. Some researchers will need to have access to these samples to store them and keep track of where they are, but these people will not have information that directly identifies you.

There is no time limit on how long your samples will be stored. We do not yet know the specific type of testing that will be done with these samples. They may be used to check that certain laboratory tests are performed correctly. We do not plan to do any testing of your genes on stored samples. Any future testing that is not related to the goals of this study will have to be approved by an Institutional Review Board/Ethics Committee (IRB/EC).

You can still be in this study if you decide that we cannot store your leftover blood. You can change your mind about storing and using these samples for future tests at any time by writing to the person in charge of this study. We will then destroy the leftover samples. But, researchers will not be able to destroy samples or information from research that is already started.

Please indicate by providing your initials in the spaces below if you agree to long-term storage and future testing of leftover blood samples.

PARTICIPANT INITIALS

_____		I DO agree to allow my leftover blood to be stored and used in future research studies.
Initials	Date	
_____		I DO NOT agree to allow my leftover blood to be stored and used in future research studies.
Initials	Date	

RISKS OF THE STUDY

10. There may be risks to being in this study.

- If you decide to take and use the HIV mail-in test kit, you may feel nervous waiting for your test result. If the test shows that you might have HIV, you may worry about your health and future.
- When we draw your blood, we will stick a needle into your arm. This may hurt for a moment, and you may have a bruise afterwards. You may feel lightheaded, or in rare cases, you may faint. There is a small chance that you could get an infection at the place the needle went into your arm.
- Some of your blood will be tested for HIV. The study staff may be required by law to report the result of these tests to the local health authority.
- Some of the questions we ask you may make you feel uncomfortable or embarrassed. However, you will be answering these questions on a tablet, a computer or your phone, so you will not have to talk about your answers with anyone. You can skip questions that make you uncomfortable.
- If you take the longer survey later, we suggest that you answer the questions in a private place. This way, others will not see your answers.
- If others find out you are in the study, they may treat you unfairly. For example, your friends or family may treat you unfairly because they think that being in the study means that you have HIV.
- Additionally, there may be unknown risks.

BENEFITS OF THE STUDY

11. There may be no direct benefit to you by being in the study.

However, what we learn from you may help us learn more about HIV in your community. This information may lead to better ways to prevent HIV in the future. You will have the choice to

receive a free HIV mail-in test kit or coupon to obtain a kit. You can use this kit yourself or give it to someone else who you think could benefit from an HIV test.

OTHER INFORMATION ABOUT THE STUDY

12. There are other ways to get HIV testing in your community.

Please ask the study staff if you would like more information about local HIV testing.

13. You may be withdrawn from the study without your consent.

This may happen if you fail to follow the instructions given by the study staff. We may also take you out of the study if the people who fund the study (NIH), conduct the study (HPTN) or review the study (institutional review board [IRB]) stop the study.

14. There is no cost to you to be in this study, and you will receive some money.

We will give you up to $xx for being in the study.

When you provide the blood draw and complete the short survey, you will receive $xx. When you complete the longer survey, you will receive: $xx. If someone who you provide a coupon to participates in the study, you will receive: $xx. If all three people who you give a coupon to bring back their coupons, you will receive a total of $xx ($xx for each person).

15. We will let you know if any new information becomes available that may make you change your mind about participating in the study.

16. We will do our best to protect your private information.

We will make every effort to protect your private information, but we cannot guarantee absolute confidentiality. We will only collect enough of your personal information to ensure that you only participate in the study one time, to provide reminders about longer survey completion as needed, and to give you your money if you recruit others to the study. None of this information will be put into the study database, and it will be kept in a locked location. In the database, your information will only be linked to a code, not your name or any other identifying information. All study staff are trained and agree not to reveal any private information you share with them. Any publication of this study will not use your name or identify you personally.

The information you provide may be reviewed to ensure the assessment is being done properly. This information may be reviewed by the HPTN and people who work for them such as the study staff. It may also be reviewed by the organization that funds this study, National Institutes of Health (NIH), its contractors and study monitors. Any Institutional Review Board(s) (IRB) overseeing this study, and US Office for Human Research Protections are allowed to review the information you provide to the study. Your records will be kept for at least 3 years after the study ends, or longer if local regulations require. Your records will be destroyed when regulations allow it.

The researchers in this study will do everything they can to protect your privacy. We have obtained a "Certificate of Confidentiality" from NIH which can be used to legally refuse to give information that would identify you to others that are not a part of the study. For example, researchers can say "No" to a court that is trying to get information about you. But the courts can make researchers give information about you to prevent serious harm to you or others.

This certificate does not stop you, or people close to you, from telling others about your participation in the study. So, you and people close to you need to protect your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

17. If you get sick or injured during the study, let us know right away.

It is unlikely that you will be injured as a result of being in the study. If you are injured, the study staff will help you right away. You may or may not have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries from the NIH. You do not give up any legal rights by signing and dating this consent form.

18. Who to contact about this study.

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact [add the name of the IoR] at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

Study Subject Adviser, Advarra IRB
6940 Columbia Gateway Drive, Suite 110. Columbia, MD 21046
or call toll free: 877-992-4724
or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: (insert PRO number)

SIGNATURE PAGE

HPTN 096
Getting to Zero among Black MSM in the American South:
Testing the Efficacy of an Integrated Strategy

FINAL Version 3.0
3 August 2023
INFORMED CONSENT/ASSENT FOR CROSS-SECTIONAL ASSESSMENT

If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to join the study, please sign your name or make your mark below.

_____	_____
Participant Name (print)	Participant Signature and Date
_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature and Date
_____	_____
Witness Name (print) (As appropriate)	Witness Signature and Date